

{Electronic Version}
Revised Interim Guidance for EPA Rulewriters:

Regulatory Flexibility Act

as amended by the

**Small Business Regulatory
Enforcement Fairness Act**

MARCH 29, 1999

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NOTICE

The statements in this document are intended solely as guidance. This document is not intended, nor can it be relied upon, to create any rights enforceable by any party in litigation with the United States. EPA may decide to follow the guidance provided in this document, or to act at variance with the guidance, based on its analysis of the specific facts presented. This guidance may be revised without public notice to reflect changes in EPA's approach to implementing the Regulatory Flexibility Act as amended by the Small Business Regulatory Enforcement Fairness Act or to clarify and update text.

*This Guidance was developed by the Regulatory Management Division of EPA's Office of Policy. To find out if we have issued corrections or revised this guidance, you can call (202) 260-5480 or EPA staff can access the Regulatory Development intranet site:
<http://intranet.epa.gov/rapids>.*



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
POLICY

MEMORANDUM

SUBJECT: Transmittal of *Revised Interim Guidance for EPA Rulewriters: Regulatory Flexibility Act as Amended by the Small Business and Regulatory Enforcement Fairness Act*

FROM: Thomas E. Kelly /s/
Small Business Advocacy Chair

TO: Assistant Administrators
Regional Administrators
General Counsel

I am pleased to provide you with the document referenced above. This revised guidance reflects the Agency's accumulated experience with the RFA, as amended by SBREFA, since we issued the previous guidance on February 5, 1997. This new edition retains much of the substance of the 1997 edition, while significantly expanding chapters on small entity outreach and the Small Business Advocacy Review Panel process.

As we did earlier, we have prepared this revised guidance for EPA managers and staff to use flexibly and with considerable judgment. We have discovered no single "magic formula" that applies equally to all situations. Even so, we are confident EPA employees will find this document even more helpful than its predecessor in sorting through the variety of issues we can expect to encounter in preparing sensible provisions that respond to the needs and limitations of small entities subject to environmental rules.

Attachment

cc: Steering Committee Representatives
Regional Regulatory Contacts

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List of Acronyms

APA	Administrative Procedure Act
CFR	Code of Federal Regulations
FRFA	Final Regulatory Flexibility Analysis
IRFA	Initial Regulatory Flexibility Analysis
NPRM	Notice of Proposed Rulemaking
OCEPA	Office of Communications, Education and Public Affairs (EPA)
OCIR	Office of Congressional and Intergovernmental Relations (EPA)
OECA	Office of Enforcement and Compliance Assurance (EPA)
OGC	Office of General Counsel
OIRA	Office of Information and Regulatory Affairs (OMB)
OMB	Office of Management and Budget
OP	Office of Policy (EPA)
ORMI	Office of Regulatory Management and Information (EPA)
RFA	Regulatory Flexibility Act
RMD	Regulatory Management Division (EPA)
SBA	Small Business Administration
SBAC	Small Business Advocacy Chair (EPA)
SBAR	Small Business Advocacy Review Panel or simply Panel
SBO	Small Business Ombudsman (EPA)
SBREFA	Small Business Regulatory Enforcement Fairness Act
SERs	Small Entity Representatives
SISNOSE	Significant economic Impact on a Substantial Number Of Small Entities

Preface.
A Quick Glimpse of this Guidance and the RFA/SBREFA Process

The purpose of this Guidance is to help you, the rulewriter, understand how the requirements of the Regulatory Flexibility Act as amended by the Small Business Regulatory Enforcement Fairness Act (RFA/SBREFA) fit into the Agency's Action Development Process.¹ You should use this guidance in conjunction with *EPA Guidelines for Implementing the Regulatory Flexibility Act*,² which details how to prepare regulatory flexibility analyses.

When EPA initiates a regulatory development project, RFA/SBREFA compliance should be near the top of the list of issues you address in your project plan or Analytic Blueprint.³ This guidance outlines the analytical and sequential process that will apply to most rules subject to the Regulatory Flexibility Act as amended by SBREFA. Figure 1 illustrates the RFA/SBREFA process for proposed rules and Figure 2 illustrates the RFA/SBREFA process for final rules.

Analyzing a Rule's Impact on Small Entities. Once you have determined that your rule is subject to the RFA (i.e., you are required to publish a notice of proposed rulemaking under the APA or any other statute), the first thing you need to do for RFA compliance is to determine what, if any, impact your rule will have on small entities. To do this, you need to screen your proposed **and** final rules by answering a series of questions posed and discussed in detail in **Chapter 2** of this guidance.

Implementing Small Entity Outreach. If the screening analysis indicates that your rule may have some impact on some small entities or that you need more information, **Chapter 3** will provide you with guidance for identifying and engaging in a dialogue with representatives of small entities that may be subject to the rule under development.

Small Business Advocacy Review Panels. If the screening analysis of your rule indicates that the rule is likely to have a significant economic impact on a substantial number of small entities, you should plan to prepare for a Small Business Advocacy Review Panel. In **Chapter 4** you will find detailed information about how you should go about complying with the requirement that the Agency convene a

¹ See *EPA's Action Development Process: Regulatory and Policy Development; Guidelines for Implementation*, July 1994, available from the Office of Policy's Regulatory Management Division (RMD) at (202) 260-5480, or EPA's Regulatory Development intranet site: <http://intranet.epa.gov/rapids>.

² This document supersedes and revokes all prior agency guidance on the Regulatory Flexibility Act as amended by the Small Business Regulatory Enforcement Fairness Act, except for the material on preparing a regulatory flexibility analysis contained in the *EPA Guidelines for Implementing the Regulatory Flexibility Act*, April 1992. The *EPA Guidelines for Implementing the Regulatory Flexibility Act* (April 1992) are available from RMD, or EPA's Regulatory Development intranet site: <http://intranet.epa.gov/rapids>.

³ See *Guidance for Analytic Blueprints*, June 1994, available from RMD, or EPA's Regulatory Development intranet site: <http://intranet.epa.gov/rapids>.

Small Business Advocacy Review Panel for proposed rules which are likely to have a significant economic impact on a substantial number of small entities.

Regulatory Flexibility Analyses. If the outcomes of your screening analysis and Panel suggest that the Agency will not certify that the rule will not have a significant economic impact on a substantial number of small entities, you must prepare an Initial Regulatory Flexibility Analysis at the proposed rule stage and a Final Regulatory Flexibility Analysis at the final rule stage. For guidance on preparing regulatory flexibility analyses, please refer to the material contained in the *EPA Guidelines for Implementing the Regulatory Flexibility Act*, April 1992.

Small Entity Compliance Guides. If you must prepare a final regulatory flexibility analysis for your **final rule** (i.e., you do not certify the rule as having no significant economic impact on a substantial number of small entities), RFA/SBREFA also requires you to prepare a small entity compliance guide. **Chapter 5** answers questions regarding what constitutes such a guide and gives guidance for designing a small entity compliance guide.

Ongoing Informal Small Entity Guidance. When planning for the post-promulgation stage of your rule, refer to the discussion in **Chapter 6** regarding the RFA/SBREFA provision on giving informal advice to small entities in response to inquiries.

Periodic Review of Rules. The SBREFA amendments to the RFA made judicially reviewable the provisions found in RFA section 610 requiring the Agency to periodically review promulgated rules which have or will have a significant economic impact upon a substantial number of small entities. **Chapter 7** explains our plans for continued compliance with this requirement.

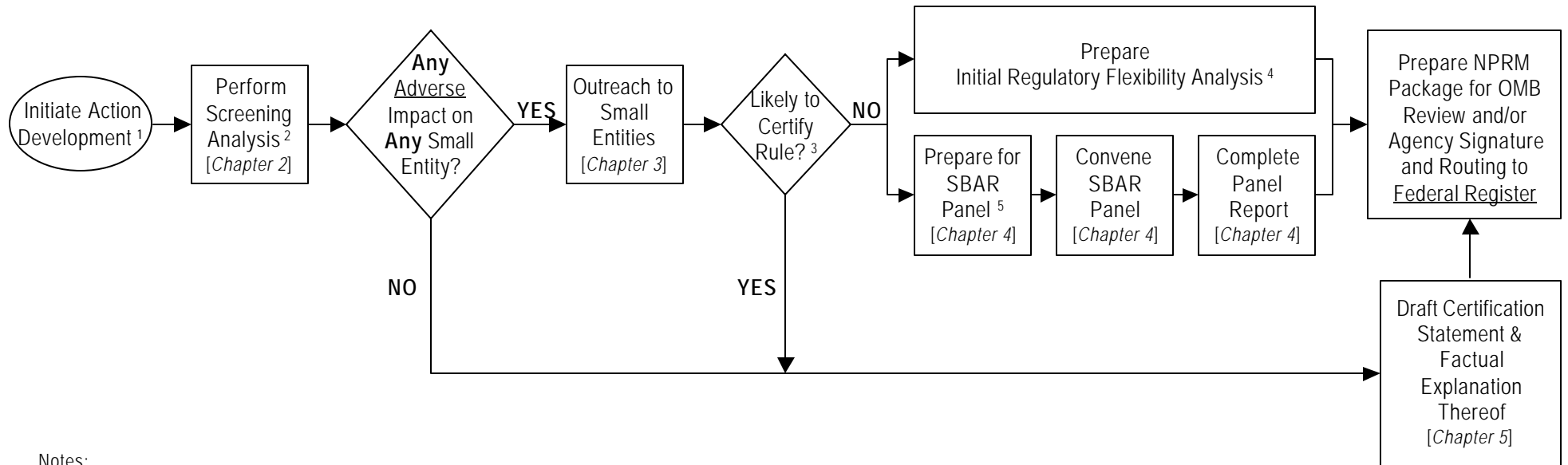
Please note: This guidance is not a binding agency procedural rule. In determining and mitigating impacts on small entities, we anticipate that there will be many situations in which agency staff and management must exercise considerable judgment. Nevertheless, we intend this guidance to provide you with an analytic and sequential structure that should be sufficient for most covered rulemakings. Should you come across a situation that does not appear to be discussed in this guidance, or a situation where an approach other than that suggested by this guidance makes sense, you may follow that approach in consultation with your Regulatory Steering Committee representative, the Office of Policy (OP) and your assigned attorney from the Office of General Counsel (OGC). We provide a list of OP and Steering Committee representative contacts in Section 3.8.

The Regulatory Management Division of EPA's Office of Policy developed this guidance for practical use. From place to place it repeats information already introduced in order to increase its accessibility and utility to a rulewriter working under pressure and looking to find adequate guidance on a particular point quickly. We apologize in advance to more leisurely readers who may find the narrative occasionally redundant for this reason. Even so, we strongly urge all users of the guidance to review it in its entirety before embarking on a rulemaking likely to directly regulate small entities.

This document supersedes and revokes all prior agency guidance on the Regulatory Flexibility

Act as amended by the Small Business Regulatory Enforcement Fairness Act, except for the material on preparing a regulatory flexibility analysis contained in the *EPA Guidelines for Implementing the Regulatory Flexibility Act*, April 1992. To find out if we have issued corrections or revised this guidance, you can call (202) 260-5480 or EPA staff can access the Regulatory Development intranet site: <http://intranet.epa.gov/rapids>.

RFA/SBREFA Process Overview For Proposed Rules



Notes:

General : References to "Chapters" in the flowchart refer to the chapters in this guidance document. See Table of Contents.

¹ Only rules subject to notice-and-comment requirements are subject to the regulatory flexibility analysis requirements of the the RFA, as amended by SBREFA. See Chapter 1 and 2 for more details.

² It may be appropriate to start outreach to small entities before or concurrent with performing a screening analysis. See Chapter 3 for more details.

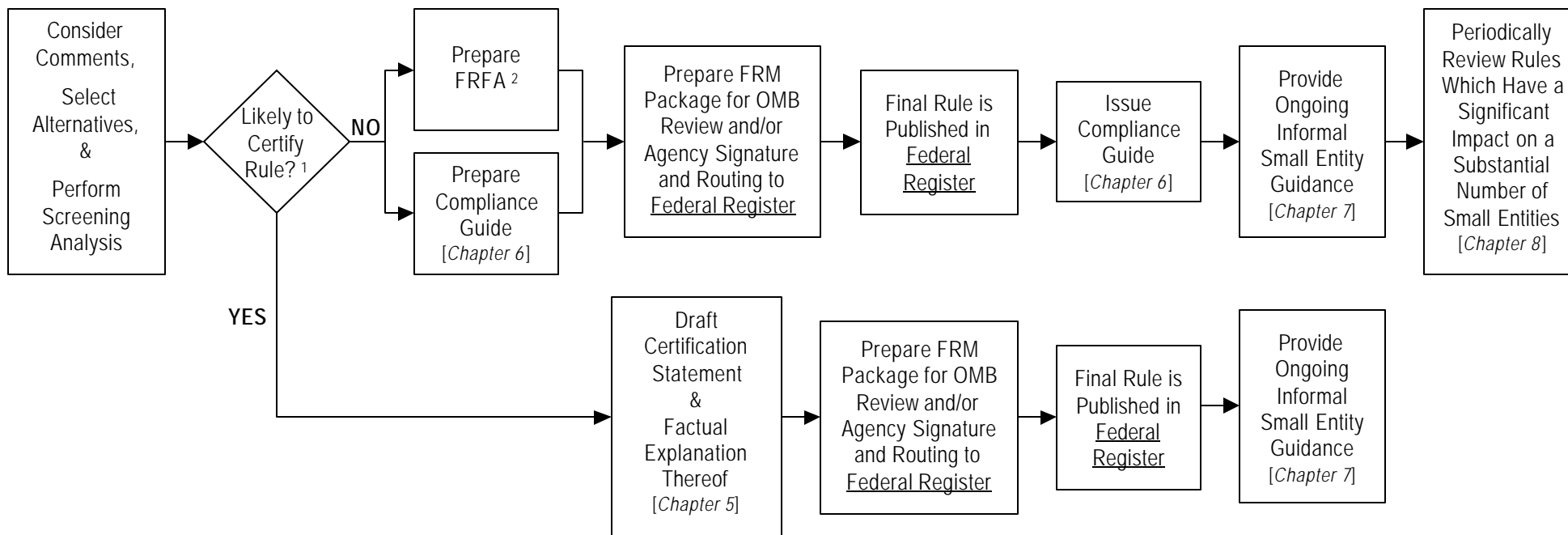
³ It is EPA's policy to assess impacts on small entities and minimize impacts to the extent feasible. If you do not have enough information to determine with confidence that the Agency can certify (no SISNOSE), proceed with "NO." The decision to certify can be made at any time before proposal.

⁴ Under the RFA/SBREFA, you must prepare an IRFA and meet other requirements for your rule proposal, unless the Administrator certifies that the rule "will not, if promulgated, have a significant economic impact on a substantial number of small entities." See Chapter 1 for general information and *EPA Guidelines for Implementing the Regulatory Flexibility Act* (April 1992) for more detailed information on preparation of an IRFA.

⁵ Although the preparation of the IRFA and the term of the Panel are represented here as concurrent activities, in reality, there is no firm linkage in timing for the two tasks.

Figure 1

RFA/SBREFA Process Overview For Final Rules



Notes:

General : References to “Chapters” in the flowchart refer to the chapters in this guidance document. See Table of Contents.

¹ It is EPA’s policy to assess impacts on small entities and minimize impacts to the extent feasible. If you do not have enough information to determine with confidence that the Agency can certify (no SISNOSE), proceed with “NO.” The decision to certify can be made at any time before proposal. If you have not gone through the RFA/SBREFA Panel process for rule proposal, but think that you may not be able to certify your final rule, consult with your OGC attorney.

² Under the RFA/SBREFA, you must prepare a FRFA and meet other requirements for your final rule, unless the Administrator certifies that the rule “will not, if promulgated, have a significant economic impact on a substantial number of small entities.” See Chapter 1 for general information and *EPA Guidelines for Implementing the Regulatory Flexibility Act* (April 1992) for more detailed information on preparation of a FRFA.

Figure 2

Chapter 1.

Introduction to the Regulatory Flexibility Act as amended by SBREFA

1.1 What is the RFA?

President Carter signed the Regulatory Flexibility Act (RFA) into law on September 19, 1980. In enacting the law, the Congress found that “uniform Federal regulatory and reporting requirements have in numerous instances imposed unnecessary and disproportionately burdensome demands . . . upon small [entities] . . . [T]he practice of treating all regulated [entities] as equivalent may lead to inefficient use of regulatory agency resources, enforcement problems and, in some cases, to actions inconsistent with the legislative intent of health, safety, environmental and economic welfare legislation.”

The RFA imposes both analytical and procedural requirements on EPA and other federal agencies. The analytical requirements call for EPA to carefully consider the economic impacts our rules will have on small entities. The procedural requirements are intended to ensure that small entities have a voice when EPA makes policy determinations in shaping its rules. Together, these requirements ensure that EPA carefully considers the effect our regulations may have on small entities. However, the RFA's analytical and procedural requirements do not require EPA to reach any particular result regarding small entities.

1.2 What is SBREFA?

SBREFA is the Small Business Regulatory Enforcement Fairness Act, a regulatory reform statute passed by the 104th Congress and signed into law by President Clinton on March 29, 1996. SBREFA (Pub Law No. 104-121) enacted a variety of provisions, including several amendments to the Regulatory Flexibility Act, 5 U.S.C. §§ 601 et seq., of particular importance to EPA rulemakings. The statute is now known as the Reg Flex Act as amended by SBREFA, RFA/SBREFA or just the RFA.

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1.3 What Do I Need to Know about RFA/SBREFA?

In short, SBREFA amended the Regulatory Flexibility Act (RFA) to establish certain formal procedural and analytical requirements (detailed below) for the limited number of rules developed by EPA with the potential to impose a significant economic impact on a substantial number of small entities.⁴ More specifically, as a rulewriter, if your rule will impose a significant economic impact on a substantial number of small entities (see Chapter 2) you most likely will be required to prepare a formal analysis of the potential adverse economic impacts on small entities, participate in a Small Business Advocacy Review Panel (proposed rule stage), and prepare a Small Entity Compliance Guide (final rule stage).

SBREFA also made other changes to agency regulatory practice as it affects small entities. Many Agency actions under the RFA are now judicially reviewable, including decisions to certify a rule as not having a significant impact on a substantial number of small entities, the preparation of a regulatory flexibility analysis and periodic review of final rules. SBREFA's other provisions include Subtitles A through C, relating to enforcement of federal laws and regulations with respect to small entities, and Subtitle E, wholly unrelated to the small entity provisions of the rest of SBREFA, which provides for Congressional review of virtually all final rules.⁵

The Regulatory Flexibility Act (RFA) was amended by the Small Business Regulatory Flexibility Act (SBREFA) in 1996. The statute is now known as: the Reg Flex Act as amended by SBREFA, RFA/SBREFA or just the RFA.

The purpose of the RFA/SBREFA is “to fit regulatory and informational requirements to the scale of the business, organizations and governmental jurisdictions subject to the regulation.” To achieve this principle, agencies are required to “solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.” The RFA/SBREFA does not require an agency to necessarily minimize a rule's impact on small entities if there are legal, policy, factual or other reasons for not doing so. The RFA/SBREFA requires only that

⁴ The Regulatory Flexibility Act definition of small entities includes small businesses, small governments and small organizations. The RFA references the definition of small business found in the Small Business Act, which authorizes the Small Business Administration (SBA) to further define small business by regulation. The SBA's small business definitions are codified at 13 CFR §121.201. More information on the definition of “small” can be found in Chapter 2.

⁵ Congressional review was previously discussed in Chapter 5 of our 1997 SBREFA Guidance. EPA's guidance on Congressional Review is now a freestanding document entitled *Congressional Review Act, Guidance for Rule Writers*, June 1998, available from the Office of Policy, Regulatory Management Division on (202) 260-5480 or on EPA's Regulatory Development intranet site: <http://intranet.epa.gov/rapids>.

agencies determine, to the extent feasible, the rule's economic impact on small entities, explore regulatory options for reducing any significant economic impact on a substantial number of such entities, and explain their ultimate choice of regulatory approach.

1.4 What is EPA's Policy for Implementing the Regulatory Flexibility Act as Amended by SBREFA?

Since its enactment in 1980, the RFA has required every federal agency to prepare regulatory flexibility analyses for any rule for which the agency is required to issue a notice of proposed rulemaking under the Administrative Procedure Act or any other statute unless the agency certifies that the rule “will

It remains EPA policy that program offices should assess the direct impact of every rule on small entities and minimize any adverse impact to the extent feasible, regardless of the size of the impact or number of small

not, if promulgated, have a significant economic impact on a substantial number of small entities.” One important function of this guidance is to establish workable guidelines for determining if a particular rule will have a “significant impact” on a “substantial number” of small entities. Prior to the enactment of SBREFA, EPA exceeded the requirements of the RFA by preparing regulatory flexibility analyses for every rule that would have any impact on any number of small entities, regardless of the size of impact or the number of small entities affected. That policy is embodied in the *EPA Guidelines for Implementing the Regulatory Flexibility Act* guidance document dated April 1992 (1992 RFA Guidance).⁶

When SBREFA became law in 1996, we developed additional procedures for full compliance with SBREFA’s multiple and various provisions. To ensure the Agency gave top priority to this effort, a cross-Agency Task Force was established to develop comprehensive procedures for our implementation of SBREFA. The efforts of the Task Force were reflected in the *EPA Interim Guidance for Implementing the Small Business Regulatory Enforcement Fairness Act and Related Provisions of the Regulatory Flexibility Act* guidance document dated February 5, 1997 (1997 Interim SBREFA Guidance). This guidance document updates and replaces the 1997 Interim Guidance. A summary of the changes made to the 1997 Interim SBREFA Guidance is provided in Section 1.10.

It remains EPA policy that program offices should assess the direct impact of every

⁶ This document supersedes and revokes all prior agency guidance on the Regulatory Flexibility Act as amended by the Small Business Regulatory Enforcement Fairness Act, except for the material on preparing a regulatory flexibility analysis contained in the *EPA Guidelines for Implementing the Regulatory Flexibility Act*, April 1992.

rule on small entities and minimize any adverse impact to the extent feasible, regardless of the magnitude of the impact or number of small entities affected. In view of the changes made by SBREFA, however, the Agency decided to implement the RFA as written; that is, a regulatory flexibility analysis as specified by the RFA will **not** be required simply because the rule has some impact on some number of small entities. Instead, such analyses will be required only in cases where we will not certify that the rule will not have a **significant** economic impact on a **substantial** number of small entities. This approach allows us to manage our resources such that we can consider the potential small entity impacts of all rules while preparing full regulatory flexibility analyses for those rules warranting such analyses under the RFA.

The SBREFA amendments also directed agencies to name a Small Business Advocacy Chairperson (SBAC) to act as permanent chair of their review panels. EPA's Small Business Advocacy Chair is responsible for convening Small Business Advocacy Review (SBAR) Panels and, among other things, overseeing policy decisions regarding certification that a rule will not have a significant economic impact on a substantial number of small entities. Chapter 4 provides detailed information on the SBAR Panel process.

1.5 What Rules Are Subject to the RFA/SBREFA?

As a threshold matter, the RFA/SBREFA requirement to prepare a regulatory flexibility analysis or a certification of no significant economic impact on a substantial number of small entities applies only to

- **proposed rules subject to notice-and-comment rulemaking requirements** under the Administrative Procedure Act (APA) or any other statute, and
- **final rules promulgated under the notice-and-comment rulemaking requirements** of the APA

Exempt from the RFA requirement to prepare either a regulatory flexibility analysis or a certification are

- agency actions that are **not** rules (e.g., orders or adjudications), and
- rules that the Agency is **not required** by statute to propose before promulgating.

Most EPA rulemakings are subject to Section 553 of the APA, which generally requires that an agency issue a notice of proposed rulemaking and take comment on a rule before issuing it. The APA, however, exempts from notice-and-comment requirements:

- rules of agency organization, procedure or practice that do not substantially affect the rights of non-agency parties
- rules for which the agency finds "for good cause" that notice and an opportunity to comment are "impracticable, unnecessary, or contrary to the public interest," and
- rules relating to agency management or personnel or to public property loans, grants,

benefits or contracts.

It should be noted that "direct final rules" (i.e., rules that the Agency issues without first proposing them, that are withdrawn if anyone files an adverse comment) are generally subject to notice-and-comment requirements and are therefore subject to the RFA requirements in this guidance. For more information on direct final rulemaking see, *Direct Final Rulemaking: Guidance for EPA Rule Writers*, prepared by EPA Office of General Counsel, Cross Cutting Issues Law Office (October, 1998) available at EPA's Regulatory Development intranet site: <http://intranet.epa.gov/rapids>.

The procedures for some EPA rulemakings are governed by other statutes. For example, many Clean Air Act (CAA) rulemakings are subject to the procedural requirements of section 307(d) of the CAA instead of the APA. In such cases, you should consult those statutes and your OGC attorney to determine if the rule is subject to the RFA's analytical requirements.

1.6 What Part of RFA/SBREFA Compliance is Judicially Reviewable?

Judicial review is the process whereby an adversely affected person can challenge an EPA final regulatory action in Federal court if the statute so allows and ask the court either to vacate or stay enforcement of the rule. During review of a rule, EPA must demonstrate that we complied with not only the substantive statutory requirements of the implementing statute (e.g., the Clean Air Act), but also all procedural requirements contained in regulatory statutes, such as the APA and RFA/SBREFA. During judicial review, EPA also must demonstrate that our interpretation of the law is reasonable in areas that we had discretion and that we had a rational basis for our regulatory decision.

The SBREFA Amendments to the RFA added provisions that now allow a *small entity* that is *adversely affected* by a final rule to seek review in court of an agency's compliance with the following RFA requirements:

- Section 601 - Establishing an alternative definition for small businesses, small governmental jurisdictions, and/or small non-profit organizations (*see* Chapter 2);
- Section 604 - Final regulatory flexibility analysis (FRFA) (*see* Section 1.9, below);
- Section 605(b) - Certification of the proposed or final rule and the factual basis for the certification (*see* Chapter 5);
- Section 608(b) - Delaying the completion of a FRFA for up to 180 days due to an emergency; and
- Section 610 - Periodic review of final rules that were not certified within ten years of promulgation (*see* Chapter 8).

The RFA gives a reviewing court broad discretion in deciding what the appropriate remedy should be if the court finds an agency has not complied with either the RFA's procedural requirements (e.g., consulting with the Small Business Administration and providing notice and an opportunity for comment before establishing an alternative small business definition) or the RFA's substantive requirements (e.g., preparing a meaningful FRFA). Such remedies may include vacating and/or remanding the rule to the agency for further action or deferring enforcement of the rule against small entities.

Thus, even if you have fulfilled the requirements of your implementing statute, have reasonably interpreted those statutory requirements in areas in which the agency has discretion to do so, have explained on the record your rationale for selecting the option you did, but you fail to comply with one or more RFA requirements or fail to adequately explain your conclusions, a reviewing court *could* decide to vacate, remand, or stay the rule on that basis. Indeed, one agency recently had a rule vacated for basing its RFA analysis on an alternative small entity definition it did not establish properly.

In addition, a rule may be challenged if the agency fails to adequately respond to adverse comments challenging any aspect of the rule. This applies to an agency's failure to respond to comments on the agency's certification, the factual basis for the certification, or the initial regulatory flexibility analysis.

1.7 What is in this Guidance?

The purpose of this Guidance is to help you, the rulewriter, to understand how the requirements of the RFA/SBREFA fit into the Agency's Action Development Process.⁷ You should use this guidance in conjunction with *EPA Guidelines for Implementing the Regulatory Flexibility Act*, April 1992, available from the Office of Policy, Regulatory Management Division on (202) 260-5480 or on EPA's Regulatory Development intranet site: <http://intranet.epa.gov/rapids>. The 1992 RFA Guidance details how to prepare a regulatory flexibility analysis.

When EPA initiates a regulatory development project, RFA/SBREFA compliance should be near the top of the list of issues you address in your project plan or Analytic Blueprint.⁸ This guidance outlines the analytical and sequential process that will apply to most rules subject to the Regulatory

⁷ See *EPA's Action Development Process: Regulatory and Policy Development; Guidelines for Implementation*, July 1994, or contact the Office of Policy's Regulatory Management Division at (202) 260-5480. EPA's Action Development Guidance can be found at EPA's Regulatory Development intranet site: <http://intranet.epa.gov/rapids>.

⁸ See *Guidance for Analytic Blueprints*, June 1994, (available at <http://intranet.epa.gov/rapids>) or contact the Office of Policy's Regulatory Management Division at (202) 260-5480.

Flexibility Act as amended by SBREFA. Figure 1 (above) illustrates the RFA/SBREFA process for proposed rules and Figure 2 (above) illustrates the RFA/SBREFA process for final rules.

Analyzing a Rule's Impact on Small Entities. Once you have determined that your rule is subject to the RFA (i.e. you are required to publish a notice of proposed rulemaking under the APA or any other statute), the first thing you need to do for RFA compliance is to determine what, if any, impact your rule will have on small entities. To do this, you need to screen your proposed **and** final rules by answering a series of questions posed and discussed in detail in **Chapter 2** of this guidance. If the results of your screening analysis indicate that the Agency will not certify that the rule will not have a significant economic impact on a substantial number of small entities, then you must prepare an Initial Regulatory Flexibility Analysis at the proposed rule stage and a Final Regulatory Flexibility Analysis at the final rule stage. For guidance on preparing regulatory flexibility analyses, please refer to the material contained in the *EPA Guidelines for Implementing the Regulatory Flexibility Act*, April 1992.

Implementing Small Entity Outreach. If the screening analysis indicates that your rule may have some impact on some small entities or that you need more information, **Chapter 3** will provide you with guidance for identifying and engaging in a dialogue with representatives of small entities that may be subject to the rule under development.

Small Business Advocacy Review Panels. If the screening analysis of your rule indicates that the rule is likely to have a significant economic impact on a substantial number of small entities, you should prepare for a Small Business Advocacy Review Panel. In **Chapter 4** you will find detailed information about how you should go about complying with the requirement that the Agency convene a Small Business Advocacy Review Panel for proposed rules which are likely to have a significant economic impact on a substantial number of small entities.

Small Entity Compliance Guides. If you must prepare a final regulatory flexibility analysis for your **final rule** (i.e. you do not certify the rule as having no significant economic impact on a substantial number of small entities), RFA/SBREFA also requires you to prepare a small entity compliance guide. **Chapter 5** answers questions regarding what constitutes such a guide and gives guidance for designing a compliance guide.

Ongoing Informal Small Entity Guidance. When planning for the post-promulgation stage of your rule, refer to the discussion in **Chapter 6** regarding the RFA/SBREFA provision on giving informal advice to small entities in response to inquiries.

Periodic Review of Rules. The SBREFA amendments to the RFA made judicially reviewable the provisions found in RFA section 610 requiring the Agency to periodically review promulgated rules which have or will have a significant economic impact upon a substantial number of small entities. **Chapter 7** explains our plans for continued compliance with this requirement.

This guidance is not a binding agency procedural rule. In determining and mitigating impacts on small entities, we anticipate that there will be many situations in which agency staff and management must exercise considerable judgment. Nevertheless, we intend this guidance to provide you with an analytic and sequential structure that should be sufficient for most covered rulemakings. Should you come across a situation that does not appear to be discussed in this guidance, or a situation where an approach other than that suggested by this guidance makes sense, you may follow that approach in consultation with your Regulatory Steering Committee representative, the Office of Policy (OP) and your assigned attorney from the Office of General Counsel (OGC). We provide a list of OP and Steering Committee representative contacts in Section 3.8. To find out if we have issued corrections or revised this guidance, you can call (202) 260-5480 or EPA staff can access the Regulatory Development intranet site: <http://intranet.epa.gov/rapids>.

1.8 What are the RFA/SBREFA Requirements for Rule Proposal?

If the RFA APPLIES to your rule and your screening analysis indicates your rule most likely WILL NOT have a significant economic impact on a substantial number of small entities:

Certification statement and statement of factual basis. You must prepare a certification statement and a statement of factual basis supporting the certification that your rule will not have a significant economic impact on a substantial number of small entities. The RFA Section 605(b) requires you to publish in the Federal Register "a statement providing the factual basis for such certification." With SBREFA, that certification and the factual basis for the certification are subject to judicial review. Accordingly, it is important that you provide sufficient detail in your factual basis to explain why the Agency is certifying the rule.

~OR~

If the RFA APPLIES to your rule and your rule most likely WILL have a significant economic impact on a substantial number of small entities:

Initial Regulatory Flexibility Analysis. Generally, the RFA/SBREFA requires EPA to **prepare** an Initial Regulatory Flexibility Analysis (IRFA) for each proposal, **unless** the Administrator **certifies** that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities (see Figure 1). You will find more detailed guidance on performing an IRFA in *EPA Guidelines for Implementing the Regulatory Flexibility Act*, April 1992, available from the Office of Policy, Regulatory Management Division on (202) 260-5480 or on EPA's Regulatory Development intranet site: <http://intranet.epa.gov/rapids>.

~AND~

Small Business Advocacy Review Panels. Under the RFA as amended by SBREFA, EPA **must convene** a Small Business Advocacy Review Panel for a rule under development, **unless** the Agency **certifies** that the rule will not impose a significant economic impact on a substantial number of small entities. Each Panel includes representatives from the Small Business Administration, the Office of Management and Budget, and EPA. The Panels conduct outreach to individuals representative of small entities likely to be subject to the rule and prepare a report to the EPA Administrator for each rulemaking on the potential small entity impacts of the rule and on potential ways to reduce those impacts (see Figure 1). More detailed information on the Small Business Advocacy Review Panel process is contained in Chapter 4.

1.9 What are the RFA/SBREFA Requirements for Final Rule Promulgation?

If the RFA APPLIES to your rule and your screening analysis indicates your rule most likely WILL NOT have a significant economic impact on a substantial number of small entities:

Certification statement and statement of factual basis. You must prepare a certification statement and a statement of factual basis to support the certification that your rule will not impose a significant economic impact on a substantial number of small entities. The RFA Section 605(b) requires you to publish in the Federal Register "a statement providing the factual basis for such certification." With SBREFA, that certification and the factual basis for the certification are subject to judicial review. Accordingly, it is important that you provide sufficient detail in your factual basis to explain why the Agency is certifying the rule.

~OR~

If your rule most likely WILL have a significant economic impact on a substantial number of small entities:

Final Regulatory Flexibility Analysis. For each rule that EPA promulgates and does not certify as having no significant economic impact on a substantial number of small entities, the Agency must prepare a Final Regulatory Flexibility Analysis (FRFA; see Figure 2). Importantly, RFA/SBREFA requires that each FRFA summarize the significant issues raised by public comments on the IRFA, assess these issues, and describe any changes made in response to the public comments. You will find more guidance on performing a FRFA in *EPA Guidelines for Implementing the Regulatory Flexibility Act*, April 1992, available from the Office of Policy, Regulatory Management Division on (202) 260-5480 or on EPA's Regulatory Development intranet site: <http://intranet.epa.gov/rapids>.

~AND~

Small Entity Compliance Guide. For each final rule where RFA/SBREFA requires preparation of a FRFA, the Agency must also issue a small entity compliance guide providing a Plain Language explanation of how to comply with the regulation (see Figure 2). More guidance on developing a small entity compliance guide can be found in Chapter 5.

1.10 How Does this Guidance Differ from the 1997 Interim SBREFA Guidance?

This guidance revises the 1997 Interim SBREFA Guidance and incorporates the lessons we have learned in the three years of RFA implementation since SBREFA was enacted. More specifically, we have

- substantially expanded the discussion of the Small Business Advocacy Review Panel process (Chapter 4) and small entity outreach (Chapter 3); and
- added chapters on informal small entity guidance (Chapter 6) and periodic review of rules (Chapter 7).

In addition, we have rewritten most of this Guidance in plain language.

This guidance document supersedes and revokes all prior agency guidance on the RFA and SBREFA, except for the material on preparing regulatory flexibility analyses contained in the 1992 RFA Guidance.

1.11 How Do I Provide Feedback on the RFA/SBREFA or this Guidance?

To provide feedback on the RFA/SBREFA or this guidance contact your Steering Committee representative or the staff of the Small Business Advocacy Chair. Contact information is provided in Section 3.8.

Chapter 2.

RFA/SBREFA Screening Analysis: Assessing Impact on Small Entities

This chapter describes a screening process for determining whether a regulatory flexibility analysis or a certification of no significant economic impact on a substantial number of small entities should be prepared for a proposed or final rule.⁹

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2.1 RFA/SBREFA: The Basics

Please refer to Chapter 1 for answers to questions such as:

- < What is the RFA?
- < What is SBREFA?
- < What do I need to know about SBREFA?
- < What is EPA's policy for implementing the Reg Flex Act as amended by SBREFA?
- < What are the RFA/SBREFA requirements for rule proposal and promulgation?

The purpose of the Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) is to ensure that, in developing rules, agencies identify and consider ways of tailoring regulations to the size of the regulated entities. The RFA/SBREFA does not require an agency to minimize a rule's impact on small entities if there are legal, policy, factual or other reasons for not doing so. The **RFA/SBREFA generally requires** that for certain rules, you

- **determine**, to the extent feasible, the rule's **economic impact** on small entities,
- **explore regulatory options** for reducing any significant economic impact on a substantial number of such entities, and
- **explain** your ultimate choice of regulatory approach.

Once you have determined that your rule is subject to the RFA/SBREFA, **it is most important for you to determine if your rule may have a significant economic impact on a substantial number of small entities**, thereby making you responsible for certain procedural requirements under the RFA, as amended by SBREFA. This chapter outlines procedures for making an initial assessment of the potential of your rule to have a significant economic impact on a substantial

⁹As noted earlier, the RFA requirement for a regulatory flexibility analysis or a certification applies only to rules subject to notice and comment requirements under the APA or other applicable statutes. If the action you are taking is something other than a notice and comment rulemaking, the RFA does not apply.

number of small entities. This process is also illustrated in Figure 3. Under RFA/SBREFA, the Agency must prepare a formal analysis of potential negative economic impacts on small entities, convene a Small Business Advocacy Review Panel (proposed rule stage), and prepare a Small Entity Compliance Guide (final rule stage) for most regulations **unless** the Agency certifies that the rule will not have a **significant economic impact on a substantial number of small entities** (SISNOSE).

This chapter of the guidance provides you with advice and direction on how to comply with the analytical requirements of the RFA as amended by SBREFA and our policy for implementing those requirements. In many respects, the advice and direction provided here go beyond what the law requires, and instead reflect Agency policy about how best to ensure that small entity concerns are considered in the rulemaking process. As we gain additional experience implementing the RFA as amended by SBREFA, we will review this guidance and revise it as appropriate.

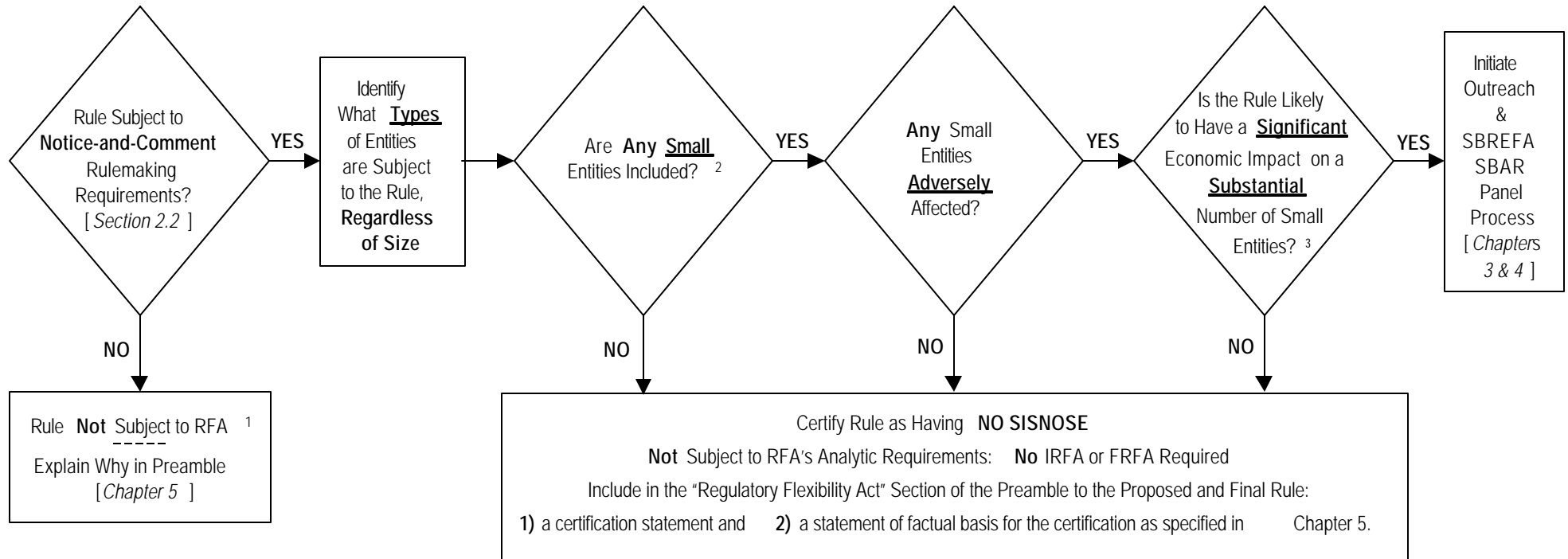
SISNOSE:
Significant economic
Impact on a
Substantial
Number
Of
Small
Entities

The RFA/SBREFA statute does not analytically define the terms *significant* or *substantial* in regard to extent of economic impact and number of small entities affected. Here we suggest guidelines for determining if a particular rule may have a SISNOSE. We recognize that there can be no one-size-fits-all methodology for making this determination. Therefore we recommend specific approaches but leave you the flexibility to use alternative methods or reach different conclusions where appropriate in the context of a

particular rule. The rationale underlying your ultimate conclusions must be included in the rulemaking record.

Where the Agency does **not** certify that a rule will have no SISNOSE, according to RFA/SBREFA you must prepare a regulatory flexibility analysis meeting the applicable statutory requirements. More information on preparation of regulatory flexibility analyses can be found in the *EPA Guidelines for Implementing the Regulatory Flexibility Act* (April 1992) available from the Office of Policy, Regulatory Management Division on (202) 260-5480 or on EPA's Regulatory Development intranet site: <http://intranet.epa.gov/rapids>. It bears repeating, however, that **even where the Agency certifies that a rule will not have a SISNOSE, EPA's policy is to make an assessment of the rule's impact on any small entities, to engage the potentially regulated entities in a dialog regarding the rule, and minimize the impact to the extent feasible.** As always, program managers should determine what level of outreach is appropriate to the expected level of impact.

Screening Analysis Process



Notes:

General: References to “Sections” in the flowchart refer to the sections in Chapter 2 in this guidance document (see Table of Contents). In addition, references to “Chapters” in the flowchart refer to the chapters in this guidance document.

¹ As a matter of Agency policy, even if your rule is not subject to RFA/SBREFA, to the extent that you foresee that your rule will have an adverse economic impact on small entities, you should assess and make efforts to minimize that impact.

² In identifying small entities, you should apply the RFA definition of small or, where applicable, any appropriate alternative definitions that the Agency has adopted or intends to adopt in accordance with the RFA. See Section 2.2 for more detail.

³ If you do not have enough information to determine with confidence that the Agency can certify (no SISNOSE), proceed with “YES.” The decision to certify can be made at any time before proposal.

Figure 3

2.1.1 What are "small entities"?

The RFA/SBREFA defines small entities as including:

- small businesses
- small governments, and
- small organizations.

The RFA/SBREFA further defines each type of small entity (detailed below), and authorizes agencies to adopt alternative definitions where appropriate in accordance with specified procedures. More information on the adoption of an alternative definition is provided in Section 2.1.2 (below).

What is a "small business"?

The RFA/SBREFA references the definition of "small business" found in the Small Business Act. The Small Business Act further authorizes the Small Business Administration (SBA) to define "small business" by regulation. The SBA's small business definitions are codified at 13 CFR 121.201; the SBA reviews and reissues those definitions every year.¹⁰ The SBA defines small business by category of business using Standard Industrial Classification (SIC) codes,¹¹ and in the case of manufacturing, generally defines small business as a business having 500 employees or fewer. For many types of manufacturing, however, the SBA's size standards define small business as a business having up to 750, 1000 or 1500 employees, depending on the particular type of business. In the case of agriculture; mining; and gas and sanitary services, the SBA size standards generally define small business with respect to annual receipts (from \$0.5 million for crops to \$25 million for certain types of pipelines). The SBA definition of a small business applies to a firm's parent company and all affiliates as a single entity.

What is a "small government"?

The RFA/SBREFA defines "small governmental jurisdiction" as the government of a city, county, town, school district or special district with a population of less than 50,000. The RFA also authorizes agencies to establish alternative definitions of small government after opportunity for public comment but consultation with the SBA is **not** required. Any alternative definition must be "appropriate to the activity of the agency" and "based on such factors as location in rural or sparsely populated areas

¹⁰ The current version of SBA's size standards can be found at:
<http://www.sba.gov/library/lawroom.html>

¹¹ Federal agencies are making the transition from the Standard Industrial Classification (SIC) system to the North American Industrial Classification (NAIC) system - further guidance will be forthcoming.

or limited revenues due to the population of such jurisdiction." Any alternative definition must be published in the Federal Register. For the purposes of the RFA, States and tribal governments are not considered small governments but rather as independent sovereigns.¹²

What is a "small organization"?

The RFA/SBREFA defines "small organization" as any "not-for-profit enterprise which is independently owned and operated and is not dominant in its field." Here again, agencies are authorized to establish alternative definitions "appropriate to the activities of the agency" after providing an opportunity for public comment (consultation with the SBA is **not** required). Any alternative definition must be published in the Federal Register.

2.1.2 When Should I Consider Establishing an Alternative Small Entity Size Standard?

Under the Small Business Act, SBA establishes size definitions for small businesses, organized by SIC code and published at 13 CFR, Part 121. In setting these definitions, SBA seeks to ensure the availability of certain government preferences, such as loan guarantees or start-up assistance to businesses under a certain size. The RFA defines small governments as those serving under 50,000 in population. Ironically, the use of these definitions in any given regulatory situation may actually defeat the Congressional intent of the RFA.

The Regulatory Flexibility Act requires that we seek reasonable accommodation of small entities, but only if we can do so and still "accomplish the stated objectives of applicable statutes," meaning for EPA the governing environmental statutes. In some cases, the number of entities defined as "small" in 13 CFR, Part 121 may be so high that the Agency can provide little or no accommodation to parties defined as small without jeopardizing our environmental objective. In such a case, the established definition may actually work against the interests of the very smallest businesses or governments, few, if any, of which may be contributing substantially to the environmental problem the regulation seeks to address. Rather than allow the existing definition of small business, government, or non-profit organization to dictate an unreasonable outcome, the Agency may consider an alternative definition that will keep the majority of polluting activities within the full scope of regulation, while

¹²Although the RFA does not require you to analyze the impacts of your rule on States and tribal governments, you may be required to analyze these impacts and/or consult with State or tribal governments in accordance with various statutes and Executive Orders such as the Unfunded Mandates Reform Act, Executive Order 12875 (*Enhancing the Intergovernmental Partnership*), and/or Executive Order 13084 (*Consultation and Coordination with Indian Tribal Governments*). Consult EPA's Regulatory Development intranet site: <http://intranet.epa.gov/rapids> and your OGC attorney for more information regarding these requirements.

affording needed flexibility to an appropriately defined sub-group of the smallest entities.

2.1.3 How Do I Establish an Alternative Small Entity Size Standard?

The RFA/SBREFA authorizes an agency to adopt and apply alternative definitions, “which are appropriate to the activities of the agency” for each category of small entity (i.e., small business, small organization and small governmental jurisdiction). To adopt an alternative definition you must provide an opportunity for public comment and publish the alternative definition in the Federal Register. To adopt an alternative definition of “small business,” you must also consult with the Chief Counsel for Advocacy of the SBA.

If you plan to adopt an alternative definition, it is extremely important to comply with these specific procedures; at least one agency recently had a rule vacated for basing its RFA analysis on an alternative small entity definition it did not properly establish. Therefore, it is imperative that you consult with your Steering Committee representative and the SBAC staff before you proceed with adoption of an alternative definition.

Moreover, you should be clear in the rulemaking notice in which an alternative definition is proposed whether you are proposing to use this alternative definition for that particular rulemaking only, for that rulemaking and any subsequent amendments, or for that rulemaking as well as all subsequent rulemakings regulating the same small entities under the same authority. If you fail to indicate this in your original proposed rule, you may be required to repeat the process for subsequent rules (i.e., give notice, take comment and, for an alternative definition of “small business,” consult with SBA). Once an alternative definition is established for a particular set of rules, you must use that definition for those rules until you adopt a different definition. Adopting a new alternative definition will involve the same process described above. Re-establishing a previous definition also requires notice and opportunity for public comment and may require consultation with SBA if re-establishing a definition for “small business.”

2.2 Performing a Screening Analysis

This section lays out our suggested RFA/SBREFA screening process step-by-step so that the relevant issues are addressed in an order that will ensure that appropriate determinations are made. You should follow this screening process for both the proposed and final versions of your rule, since the RFA generally requires that a regulatory flexibility analysis or certification be prepared for each version.

Phrased as questions, the six steps of the screening process are as follows:

Q 1.

Is the rule subject to notice-and-comment rulemaking requirements?

If your rule is **not** required by statute to undergo notice and comment, it is **not** subject to the RFA's analytical requirements and you do not need to prepare a regulatory flexibility analysis **or** a certification of no significant economic impact on a substantial number of small entities. See Section 1.5 for a more complete discussion of which rules require notice-and-comment. However, as a matter of Agency policy, even if your rule is **not** subject to the RFA/SBREFA, to the extent that you foresee that your rule will have an adverse economic impact on small entities, you should assess and make efforts to minimize that impact through consultation with the small entities likely to be regulated.

Even if your rule is **not** subject to the RFA, the preamble to the proposed rule, if any, and the preamble of the final rule should include a "Regulatory Flexibility" section that explains why the rule is not subject to the RFA.

Q 2.

What types of entities will be subject to the rule's requirements?

The RFA requires analysis of a rule's economic impact on the small entities that **will be subject to the rule's requirements**. Indeed, an IRFA or FRFA cannot be prepared for a rule that does not establish requirements applicable to small entities. The RFA requires that an IRFA or FRFA identify the types, and estimate the numbers, of small entities "to which the proposed [or final] rule will apply," and describe the rule "requirements" to which small entities "will be subject" and any regulatory alternatives, including exemptions and deferrals, which would lessen the rule's burden on small entities (see sections 603 and 604 of the RFA). Rules that do not establish requirements applicable to small entities (e.g., rules establishing or revising national ambient air quality standards under the CAA or water quality standards under the Clean Water Act) are thus not susceptible to RFA analysis and may be certified as not having a SISNOSE. Similarly, if your rule is applicable only to large entities, but small entities are among those who may experience economic effects downstream from the rule's implementation, you may certify that the rule has no SISNOSE. However, you should evaluate those "ripple" effects as part of your broader economic analysis for the rule.

If your rule is subject to statutory notice-and-comment rulemaking requirements, you should conduct and document a screening analysis. The first step in the analysis is to identify what types of entities (regardless of size) would be subject to the rule's requirements, as follows:

Businesses: Identify the types of businesses potentially subject to the rule's requirements and determine the SIC code for those types of businesses, since the SBA's size standards apply to specific SIC codes.

Governments: Identify all forms of governments potentially subject to the rule, including cities, counties, towns, townships, villages, and special districts.

Nonprofit Organizations: Identify what types of nonprofit entities such as hospitals, colleges, universities and research institutions are potentially subject to the rule.

Q 3.

What types of *small* entities, if any, will be subject to the rule’s requirements?

Of the types of entities potentially subject to any of the rule’s requirements, you should next determine the extent to which those types of entities include **small** entities. In identifying small entities, you should apply the RFA definition of small or, where applicable, any appropriate alternative definitions¹³ that the Agency has adopted or intends to adopt in accordance with the procedures established by the RFA. The RFA default definitions of small business, small government, and small non-profit organization are detailed in Section 2.1.1 (above).

Q 4.

Will *any* small entities potentially be subject to the rule’s requirements?

If **no** small entities will be subject to any of the rule’s requirements, you may certify that your rule will **not** have a significant economic impact on a substantial number of small entities on that basis. The certifications should be published and explained in the preambles of the proposed and final rules and supported in the rulemaking record as appropriate. No further analysis is required to support your certifications, unless the Agency receives comments on the proposed rule’s certification that indicate its basis is flawed.

Q 5.

Will any small entities be *adversely* affected by the rule’s requirements?

EPA believes only rules that will have a significant **adverse** economic impact on small entities require an IRFA and FRFA, since the primary purpose of both analyses is to identify and address regulatory alternatives “which **minimize** any significant economic impact of the proposed [or final] rule

¹³ The RFA grants agencies discretion to develop and apply alternative definitions of small business, small governments and small nonprofit organizations. In exercising this discretion, however, care should be taken to develop alternative definitions that identify small entities as opposed to entities that emit a small volume of pollution. It may be appropriate for the Agency to provide regulatory flexibility or relief to small-volume polluters on general policy grounds, but the focus of the RFA is on entities whose size or resources are small in comparison to other entities of their type.

on small entities.” (sections 603 and 604, emphasis added). Thus, rules that **relieve** regulatory burden, or otherwise have a positive economic effect on the small entities subject to the rule, do not require an IRFA or a FRFA.

If your rule will not have any adverse effect on any small entity subject to the rule’s requirements, you may certify that the proposed and final rules will not have a significant economic impact on a substantial number of small entities on that basis. The certifications should be published and explained in the preambles of the proposed and final rules and supported in the rulemaking record as appropriate. No further analysis is required to support the certification, unless the Agency receives comments on the proposed rule’s certification that indicate its basis is flawed. If one or more small entities subject to the rule will be adversely affected by the rule, it remains EPA policy that program offices should assess the impact on small entities and minimize any negative impact to the extent feasible, regardless of the magnitude of the impact or number of small entities affected.

It should be noted that a particular rule may reduce some burdens on small entities and create or increase burden on others. Where the rule reduces the burden on one type of small entity while increasing the burden on another type of small entity, the decrease and increase in burden generally may **not** be netted. Where both a decrease and increase in burden will occur to the same small entities, it is appropriate to consider the net impact on those small entities. For a rule that will establish requirements applicable to small entities, only the impacts of the rule on the small entities subject to the rule’s requirements need to be analyzed for RFA purposes.



Will the rule have a *significant economic impact* on a *substantial number* of small entities?

For a proposed or final rule that will have an adverse effect on one or more small entities directly subject to the rule, you must next determine the extent of the impact and the number of small entities so impacted. Both qualitative information and quantitative analysis will be relevant in making this determination.

What is the role of qualitative information?

Before investing in detailed quantitative analysis, you should describe the steps a small entity will have to take to comply with the requirements of the rule. In doing so, you will better clarify the nature of the impacts (e.g., installation of new technological processes, institution of new maintenance practices). You may then be able to deduce whether the potential impacts are of sufficient magnitude and scope to warrant requiring the preparation of an IRFA or FRFA.

If a qualitative assessment indicates that your rule is likely to have a SISNOSE, you may

choose to prepare an IRFA and FRFA on that basis and avoid the need for a full screening analysis. Where a qualitative assessment indicates that a rule will **not** have a SISNOSE, you may be able to certify the rule on that basis or you may need to conduct a quantitative analysis to confirm the results of the qualitative assessment. For example, where the information necessary to conduct a quantitative analysis is not reasonably available, it may be appropriate to certify the rule based on the qualitative assessment alone. Since the decision to certify a rule is judicially reviewable, you should expect to prepare a quantitative analysis whenever possible to support such a conclusion. **You should consult with your Steering Committee representative and the Small Business Advocacy Chair when you anticipate relying on qualitative analysis to certify a rule.**

How should I conduct a quantitative analysis?

The Agency is in the final stages of revising its *Guidelines for Preparing Economic Analyses*¹⁴, once these are formally issued, you should follow the relevant procedures for calculating costs, as outlined in Chapter 9 of the *Guidelines*, for the purposes of your screening analysis. The *Guidelines* detail a process for considering equity and distributional concerns as a component in rulemakings and small entity impacts are a specific sub-set of these concerns that are directly addressed in Chapter 9.

What measures of economic impact should I use?

The table below (Table 1) lists our current suggested economic guidelines for assessing the impact of a rule on small entities. The suggested guidelines are drawn from standard economic analyses and vary by type of small entity in view of the different economic characteristics of small businesses, small governments, and small nonprofit organizations. The value of the denominator of the quantitative screening guidelines should be based on an average of at least three years of data when possible and practical. Further, for each type of small entity, more than one approach is listed. The guidelines vary in terms of the type of data involved, and thus you may choose to apply one over the others based on the type of information available. The table nevertheless indicates a preferred guideline for each type of small entity (i.e., B1, G1 and N1).

Conceptually, we believe that a profits test represents the most accurate screening analysis for determining whether a regulation will pose a significant economic burden on small businesses. However, because of procedural and operational issues associated with the implementation of a profits test, a sales test remains our preferred quantitative guideline at this time. Because data on profits are limited, especially for small businesses, routine use of a profits test would require us to estimate profits

¹⁴ At the time of publication, this document is under review. To obtain more information on final release or availability of copies call EPA's Office of Economy and Environment at (202) 260-3354.

for small businesses where there are currently insufficient data. For example, sufficient data are unlikely to exist across all SIC codes that a regulation affects. This would limit our ability to rely on consistent information to determine the magnitude and scope of economic impacts on small business, both for a single regulation and across regulations. We remain committed to developing the ability to implement the most accurate screening analysis possible and to establishing a process to implement a profits test. Our goal is to develop a profits test that may be used in addition to, or in preference to, the sales test when there are sufficient reliable data to support it and the procedural and operational issues have been resolved.

You should use the preferred guidelines listed in Table 1 because they are logistically simple to apply and data are more readily available to allow consistent applications from rule to rule. You may nonetheless use one of the other guidelines, or even a guideline not included in the table, where you have sound reasons for doing so and can explain those reasons in the rulemaking record.¹⁵ Further, when data are available to support other relevant measures of impact other than the preferred guideline (or its listed substitute), we encourage you to use them to supplement your analysis.

To what extent should my analysis differentiate among types of small businesses, small governments or small nonprofits?

A rule may apply to more than one kind of business, government, or nonprofit organization. For example, a rule may apply the same requirements to printers, dry cleaners, and auto-body shops. In assessing the impact of such a rule on “small business,” it may be appropriate to analyze the rule’s impact on each kind of business separately, particularly where the rule may impose significantly higher costs on some kinds of businesses than on others. However, as described in more detail below, for the purposes of deciding if preparation of a regulatory flexibility analysis or a certification is required, the impacts of the rule, once assessed for the two types of business, should be aggregated and the aggregates fed into the matrix presented in Table 2.

¹⁵When applying any alternative quantitative guidelines other than the preferred approach, you must consult with your Steering Committee representative and the Small Business Advocacy Chairperson (SBAC), the OP’s Office of Economy and Environment and other relevant Agency offices (including those identified by the SBAC) in determining the level at which the impact may warrant requiring preparation of a regulatory flexibility analysis.

TABLE 1: Recommended Quantitative Guidelines for Evaluating the Economic Impact of a Rule on Small Entities

Type of Entity and Guidelines (preferred guidelines in <i>bold italics</i>) ¹	
SMALL BUSINESSES	
<i>B.1</i>	<i>Annualized compliance costs as a percentage of sales ("Sales Test")</i>
B.2	Debt-financed capital compliance costs relative to current cash flow ("Cash Flow Test")
B.3	Annualized compliance costs as a percentage of before-tax profits ("Profit Test")
SMALL GOVERNMENTS	
<i>G.1</i>	<i>Annualized compliance costs as a percentage of annual government revenues ("Revenue Test")</i>
G.2	Annualized compliance costs to household (per capita) as a percentage of median household (per capita) income ("Income Test")
SMALL NONPROFIT ORGANIZATIONS	
<i>N.1</i>	<i>Annualized compliance costs as a percentage of annual operating expenditures ("Expenditure Test")</i>
N.2	Annualized compliance costs as a percentage of total assets ("Asset Test")
¹ When applying any quantitative guidelines other than the preferred approach, you must consult with your Steering Committee representative and the Small Business Advocacy Chairperson (SBAC), the OP's Office of Economy and Environment and other relevant Agency offices (including those identified by the SBAC) in determining the level at which the impact may warrant requiring preparation of a regulatory flexibility analysis.	

For proposed rules, what should I analyze if more than one regulatory approach is being proposed or seriously considered?

For proposed rules, one of the guidelines listed in Table 1, or any other economic guideline you decide to use, should be applied to the regulatory approach in the proposal. **Where you plan to propose multiple regulatory alternatives (i.e., two or more approaches from among which one will be selected for promulgation in the final rule), you should apply the guidelines to each of the proposed alternatives and at a minimum to the alternative that would likely have the greatest impact on small entities.**

Similarly, if you plan to propose a single regulatory approach but seek comment on variations

of that approach or on different approaches altogether, **you should ordinarily analyze not only the proposed approach but also the potentially most burdensome variation or approach that has a significant chance of being promulgated.** You should contact your Steering Committee representative and your OGC contact when uncertain about the appropriate scope of an IRFA for a proposed rule.

In assessing costs, should I assume compliance with existing legal requirements? Should I assess incremental or cumulative costs?

Yes, in calculating the costs the rule will impose on small entities, you should presume full compliance with all existing applicable statutory or regulatory requirements. Generally, in the case of a rule revising an existing rule, you should assess only the incremental cost of the rule revision because the cost of the existing rule was assessed, and a regulatory flexibility analysis or certification prepared, when the rule was developed. However, there may be some unique circumstances where the presumption of full compliance may not be appropriate. In such cases, you should consult with your Steering Committee representative, the SBAC and OGC before conducting the analysis.

Using the economic guidelines suggested in Table 1, what degree and extent of impact constitute “a significant economic impact on a substantial number of small entities”?

Application of the guidelines suggested above to a particular rule will yield quantitative estimates of the rule's impact on small entities. Table 2 presents a matrix that categorizes the rule based on the magnitude of its impact (as measured using the preferred guidelines) **and** the number of entities expected to experience the impact. Each category establishes either a process or a presumption regarding whether a rule can be certified as having no SISNOSE. The categories are as follows:

- Category 1:** The rule is presumed **not** to have a significant economic impact on a substantial number of small entities, but your Assistant Administrator may, at his or her discretion, decide to prepare a regulatory flexibility analysis for the rule.
- Category 2:** No presumption applies. You must consult with the Small Business Advocacy Chair if you believe that your rule should be certified as **not** having a significant impact on a substantial number of small entities. You may recommend (through your Steering Committee representative) certification to the SBAC and provide the SBAC with information and analysis supporting your recommendation.
- Category 3:** The rule is presumed to be ineligible for certification, so you should contact the SBAC through your Steering Committee representative, prepare a regulatory flexibility analysis

and participate in a Small Business Advocacy Review Panel.¹⁶

The scope of each category is defined by various thresholds for three variables:

- the magnitude of the economic impact,
- the absolute number of small entities that will experience that impact, and
- the percentage of small entities that will experience that impact.

It is important to keep in mind, however, that these are only guidelines for assessing if a rule may have a SISNOSE. The RFA itself does not establish a formula for making this determination, and indeed, it would be impossible to develop a formula that would yield an appropriate answer in the context of every rule. For that reason, the guidelines suggest categories that establish no more than a presumption. Agency management may exercise judgment in deciding whether to prepare an IRFA or FRFA or to certify your rule. Indeed, the Agency has already employed such discretion by choosing not to certify a proposed rule that directly regulated fewer than 100 small businesses, but with an impact considerably greater than 3% of sales. Another such case is currently pending. With more information and experience, the Agency may conclude that the guidelines defining the categories should themselves be changed. For the time being, however, we believe the guidelines used in Table 2, have been successfully and flexibly applied over the past two years, and remain useful as initial referents in determining whether a rule is likely to have a SISNOSE.

Should I apply the Table 2 matrix separately to each type of small entity subject to the rule?

Yes, where the rule will apply to more than one type of small entity (i.e., small businesses, small governments, or small nonprofit organizations), you should apply the matrix from Table 2 separately to each type subject to the rule. For example, for a rule that will impose the same (or substantially similar) requirements on small businesses and small governments, you should analyze the rule's impact on small businesses using an economic guideline appropriate to small businesses, and analyze the impact on small governments using a guideline appropriate to small governments. You should then feed the results of each analysis into the matrix separately. The rule will thus be categorized twice -- once for its impact on small businesses and a second time for its impact on small governments.

Under this approach, it is possible that a rule may fall into Category 1 with respect to one type of small entity and Category 2 (or 3) with respect to another type. This could be the case, for example, where the rule's impact would be less than 1% of sales for small businesses (Category 1), but 2% of

¹⁶To overcome the presumption that a rule falling in Category 3 will have a significant impact, additional quantitative analysis may be necessary. For examples of types of additional quantitative analysis that could provide further information, see *EPA Guidelines for Implementing the Regulatory Flexibility Act* (April 1992) sections IV and VI, and Appendix E.

revenues for over 1000 small governments (Category 2). Where a rule falls into more than one category, the rule should be placed in the highest category into which it falls. Thus, in the above example, the rule would be considered a Category 2 rule, and the Agency would approach the decision about whether to prepare a regulatory flexibility analysis or a certification for the rule in accordance with the guidelines for Category 2 rules. The RFA does **not** require that you decide whether to prepare an analysis or a certification based on the rule's impact on the type of small entity most affected by the rule, but EPA has chosen to take this approach to ensure that we identify and address potentially significant impacts on any one type of small entity.

Where a rule applies to more than one type of small entity, and separate application of the table places the rule in Category 1, one further analytic step is required to categorize the rule: aggregation of the results of the impact analyses on the different types of affected small entities and application of the matrix to the aggregated results. This step is necessary because the table uses absolute numbers as well as percentages to assess whether the rule is likely to impact a substantial number of small entities. The absolute numbers provide a suggested floor and ceiling for what may constitute a substantial number. For example, a rule that imposes a significant economic impact on over 1000 small entities is presumed to meet the "substantial number" guideline even if that number represents less than 20% of affected small entities.

We chose these absolute numbers as indicative of a substantial number not only with respect to any one type of small entity, but with respect to **all** small entities taken together. Thus, a rule with an impact of 2% of sales, revenues or assets with respect to 334 small businesses, 334 small governments and 334 small nonprofits, where 334 is less than 20% of each type of small entity, would be a Category 1 rule if each type of small entity were looked at separately, but should be a Category 2 rule since more than 1000 small entities may be significantly affected by the rule.

The issue of applying the matrix to each type of small entity may be taken one step further -- that is, **you should apply the matrix separately to different kinds of small businesses, small governments, or small nonprofits**. A rule may, for example, apply the same requirements to dry cleaners and auto-body shops, but the rule's economic impact may be much greater on one than on the other kind of business. As indicated above, it would be appropriate in such a case to analyze the impact of the rule separately for the two kinds of business. For purposes of deciding whether to prepare a regulatory flexibility analysis or a certification, however, the impacts of the rule, once assessed for the two kinds of business, should be aggregated and the aggregates fed into the matrix. Please note that if your rule is certified, the Agency is assuring the public that the rule will not impose a significant impact on a substantial number of small entities of all types taken together. **It is not appropriate to prepare separate certifications for small businesses, small governments, and small non-profit organizations.**

How does my screening analysis relate to a Regulatory Flexibility Analysis?

If a decision is made to conduct a regulatory flexibility analysis for the small businesses subject to the rule, the analysis may address the two kinds of businesses separately. Indeed, such a disaggregated analysis is likely to improve your ability to identify ways of tailoring rule requirements to the different characteristics of the affected small businesses.

Moreover, any regulatory flexibility analysis or certification you prepare for a rule should generally cover the rule's impact on **all** types of small entities subject to the same (or substantially similar) rule requirements, even if only one type of small entity may be significantly affected in substantial numbers. We believe that if one type of small entity warrants analysis, it is generally prudent to include all types of affected small entities in the regulatory flexibility analysis and the Panel process that accompanies preparation of the initial regulatory flexibility analysis for the rule. At the same time, as previously noted, any regulatory flexibility analysis prepared for a rule may analyze and address the rule's impact on each type of small entity separately, particularly where the degree and extent of impact varies with the type of small entity.

Finally, your regulatory flexibility analysis need only explore regulatory alternatives for those types of small entities that would otherwise be significantly impacted by the rule in substantial numbers. The RFA provisions for initial regulatory flexibility analyses require that the Agency discuss any significant regulatory alternatives which “minimize any significant economic impact” of the proposed rule (section 603(c) (emphasis added)). For final rules, the RFA requires that final regulatory flexibility analyses describe “the steps the agency has taken to minimize the significant economic impact on small entities” (section 604(a)(5) (emphasis added)). Thus, you are legally required to describe and address significant regulatory alternatives only with respect to those types of small entities that may be significantly affected by the rule in substantial numbers. As per EPA policy, however, you should continue to consider and adopt ways of minimizing a rule's burden on any small entities to the extent practicable.

Are Table 2's listed outcomes mutually exclusive?

No, as indicated above, the matrix relates three variables in suggesting the appropriate category for your rule. For example, the matrix categorizes a rule based on whether it will have an impact of more than 1% of sales or revenues on less than 100, 100 to 999, or 1000 or more small entities **and** whether the absolute number of small entities so impacted is 20% or more of all affected small entities. In applying the matrix to a rule, it is important to note that the outcomes set forth in the matrix are **not** mutually exclusive. Your rule may have an impact of 2% of sales or revenues for 1000 small entities representing 40% of affected small entities (placing it in category 2) **and** 4% of sales or revenues for 500 small entities representing 20% of small entities (placing it in category 3). If a rule's impact falls into more than one category, place your rule in the highest category.

TABLE 2: Summary of Quantitative Information Used to Identify Applicable Categories for the Preferred Quantitative Guideline¹

Quantitative Guidelines			Regulatory Process Category ²
Economic Impact Condition (based on preferred guidelines from Table 1)	Number of Small Entities Experiencing Economic Impact Condition	Number of Small Entities Experiencing Economic Impact (as a Percentage of All Affected Small Entities)	
Less than 1% for all affected small entities	Any number	Any percent	Category 1
1% or greater for one or more small entities ³	Fewer than 100	Any percent	Category 1
	100 to 999	Less than 20%	Category 1
	100 to 999	20% or more	Category 2
	1000 or more ⁴	Any percent	Category 2
3% or greater for one or more small entities	Fewer than 100	Any percent	Category 1
	100 to 999	Less than 20%	Category 2
	100 to 999	20% or more	Category 3
	1000 or more ⁴	Any percent	Category 3
<p>¹ Nothing in this table on applying quantitative measures of economic impacts and enumerating the number of impacted small entities should be interpreted as indicating that the certification decision is strictly or solely based upon application of the above quantitative steps. Additional information and other factors may be relevant in deciding whether to prepare a regulatory flexibility analysis or certify under the RFA.</p> <p>² There may be cases where the extent of the impact (measured in quantitative or qualitative terms) is particularly severe, even though the number of affected small entities totals fewer than 100 or 20% of all affected small entities. In such cases, the lead office should consider placing the rule in a higher category than would otherwise be applicable.</p> <p>³ For purposes of applying this portion of the table, the number of small entities that will experience an impact of 1% to 3% should be aggregated with the number of small entities that will experience an impact of 3% or greater. The total number of small entities that will experience an impact of 1% or greater should be used here in order to determine whether the number of small entities so impacted is large enough to warrant preparation of a regulatory flexibility analysis.</p> <p>⁴ As the number of small entities that will be affected by a rule by more than 1% of sales or revenues approaches 1000 in number, the substantial number guidelines of 20% of affected small entities may become less relevant in determining whether a regulatory flexibility analysis or a certification should be prepared.</p>			

2.3 What Should I Do After Applying the Matrix?

As noted above, the guidelines set forth by this guidance cannot be applied mechanistically. You may factor additional information into the decision to certify your rule as having no significant economic impact on a substantial number of small entities. The following sections explore some of the common factors that may be relevant in deciding whether or not to certify a rule under the RFA/SBREFA.

Would an alternative definition of “substantial number” be appropriate?

When application of the matrix suggests that a rule will not impact a "substantial number" of small entities, it is appropriate for you to consider whether alternative approaches to defining "substantial number" should apply for one of the following reasons:

- ! Where the extent of the impacts, measured in economic or non-economic terms, would be of sufficient magnitude (e.g., potential collapse of a viable regionally-concentrated fraction of an industrial sector) to warrant using either a smaller absolute number (i.e., a figure lower than 100) or a smaller fraction of small entities (i.e., a figure lower than 20%).
- ! Where the size and distribution of entities within the industry, the distribution of revenues, market share, etc., suggest an alternative definition of “substantial number” for businesses. In such cases, it may not be possible or appropriate to determine whether a "substantial number" will be affected until after collecting the data necessary to prepare an IRFA or FRFA and analyzing the data for this purpose.

Should I analyze relative impacts?

Comparing a rule’s impacts on small entities versus large entities (i.e., a rule’s disproportionate impact on small entities) may be one analytical means of providing additional insight into whether a rule will have a "significant impact" on a "substantial number" of small entities. Analytical tests and guidelines for making relative comparisons are listed in section V of *EPA Guidelines for Implementing the Regulatory Flexibility Act* (April 1992).

Are there other qualitative considerations relevant at this stage?

You may factor qualitative information into this phase of determining whether a rule will not have a significant economic impact on a substantial number of small entities. Qualitative assessment of the impacts on small entities ensures consideration of legitimate non-quantitative factors that may or may

not be supported through data. Qualitative analysis can take on the appearance of a quantitative analysis, such as when the program office uses its judgment to make use of related summary data or "model" financial data in the absence of more detailed information. For example, where you cannot obtain data for a particular type of small entity subject to the rule, you may choose to use quantitative information on another type of small entity whose behavior and financial characteristics are similar to those subject to the rule. Another example might entail the creation of baseline financial characteristics for a set of small entities drawing upon quantitative information available on larger entities in the same industrial or governmental sector. You can also draw your general patterns of comparison between larger and smaller entities so as to infer the small entities' financial characteristics. In general, where quantitative information is sought, the goal is to obtain the type of data that allow for the most reliable form of quantitative analysis to be used. But where data limitations persist, we encourage adoption of reliable alternatives.

Should the screening analysis be reviewed within the Agency?

The Assistant Administrator of the office preparing a screening analysis is responsible for ensuring the integrity and validity of the screening analysis. Your AA may decide to have your screening analysis reviewed by workgroup members, or OP's Office of Economy and Environment, (OEE) and the Small Business Advocacy Chair.

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Chapter 3. Implementing Small Entity Outreach: Informing, Listening, Responding

3.1 Small Entity Outreach: The Basics

The Small Business Regulatory Enforcement Fairness Act (SBREFA) amended the Regulatory Flexibility Act (RFA) to bolster the RFA's requirements that agencies provide small entities with a meaningful opportunity to participate in the development of rules that may significantly affect them. EPA's success in carrying out our obligations under the RFA/SBREFA requires early and continuing interaction with small entities throughout the regulatory development process. The RFA/SBREFA process, and your interactions with small entities in general, should be a genuine dialogue with meaningful engagement and exchange of ideas and information. The goal of small entity outreach is to ensure promulgation of a rule that is tailored to achieve a specific environmental goal while taking into account the particular concerns of small entities.¹⁷

Early outreach and accommodation of small entity issues has proven to have a substantial positive impact on the quality of regulations.

It is important that outreach to small entities occur as early as possible in regulation development. Indeed, it will often be appropriate to start outreach before or concurrently with performance of a preliminary screening analysis (see Figure 1). Early outreach and accommodation of small entity issues has proven to have a substantial positive impact on the quality of our regulations. First, small entities can often fill gaps in our knowledge and experience to provide alternate, less burdensome regulatory options that will accomplish a stated environmental goal. Second, you can gain support for the regulatory option ultimately selected by bringing small entities into the process early on, listening and responding to their concerns, and having that input influence the direction of your rule. When you believe your rule is likely to have a significant economic impact on a

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¹⁷As a practical matter, most of the outreach we describe in this chapter will take place in the pre-proposal phase of the rule development process. While further outreach may be appropriate in the post-proposal stage, any contact with small entities at that time is subject to the same ex parte restrictions that govern all external contacts once the public comment period closes.

substantial number of small entities (SISNOSE), this early involvement should also include OGC and staff to the Agency's Small Business Advocacy Chair (SBAC, contact information below). At a later point it will be appropriate to involve the Small Business Administration's (SBA) Office of Advocacy and the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs.

Detailed below is a strategy outlining how you can identify and engage in dialogue with representatives of small entities that may be subject to your rule.

3.2 What does "Outreach" mean?

According to the *EPA Manual on Consultative Processes*,¹⁸

Outreach is a means by which the Agency keeps its constituencies - those who are interested in or affected by its action - informed about what it is doing, what it is planning, and what its needs are. Outreach is basic communication. In addition to informing those affected of the Agency's activities, outreach also encourages and provides the means by which members of the public can communicate their needs and desires to the Agency so they may be taken into account when making decisions.

In sum, outreach includes informing potentially regulated parties about EPA's regulatory plans, listening to their concerns and suggestions about how the rule may affect them, and responding through appropriate action to meet environmental objectives while minimizing unnecessary burden.

There are many forms and styles available for providing information to small entities potentially subject to a rule, including:

- public announcements
- interviews
- informal and formal meetings
- web sites and list serves
- magazine and journal articles
- speeches
- dockets, and
- press releases.

While each of these can be used to transmit necessary information to members of the public, simply providing notice of EPA's intent is not enough. Adequate outreach also requires that we seek opportunities for genuine engagement that places the Agency in a position to hear from and respond to small entities.

¹⁸*EPA Manual on Consultative Processes: Better Decisions Through Consultation and Collaboration*, Draft - October 1998, copies available from Debbie Dalton at 202.260.5495

3.3 Is Small-Entity Outreach Subject to FACA?

Some forms of outreach are regulated by statute. Specifically, the Federal Advisory Committee Act (FACA) establishes requirements for the convening and operating an official advisory committee. However, many groups are exempt from FACA coverage including: fact-finding and information exchange groups, meetings with persons providing individual advice or recommendations (as opposed to collective advice or recommendations); and, meetings with groups of people to interactively discuss and debate individual opinions or recommendations.¹⁹

RFA/SBREFA outreach has commonly occurred in the form of information exchanges. According to the *EPA Manual on Consultative Processes*, information exchanges primarily seek to enhance the parties' understanding of the situation. During information exchanges, at least one side will be providing information or advice to the other and oftentimes there will be an exchange of views or concerns. Importantly, the participants involved in information exchanges are not expected to reach agreement. Sections 3.4 and 3.6 (below) provide more specific information on where to get assistance with your outreach efforts and steps to take to reach small entities.

3.4 Should I Coordinate My Stakeholder Involvement Activities?

You are strongly encouraged to coordinate your stakeholder activities and allow these distinct processes -- internal workgroup, peer review, FACA committee, SBAR Panel -- to inform each other. Although each group has its own policies and procedures, they do not take place in isolation; indeed, they may have overlapping membership. Moreover, every stakeholder activity is based on relationships, and the relationships you develop rely on trust. Consequently, you will have greater success if you demonstrate a willingness to share information not only with your stakeholders but also between your stakeholder groups to nurture that trust. Beyond the importance of these considerations, you need to make the most of your time and resources. As you invest time at the outset of your rulemaking to develop an Analytic Blueprint or other planning document for your rule, you should be able to recognize some efficiencies in coordinating some of your stakeholder activities. For example, if you engage a contractor to assist you in identifying participants for a FACA committee, as part of the same effort, the contractor may be able to identify a group of potential small entities for a SBAR Panel. Similarly, outreach documents prepared for one

A stakeholder involvement process is not an end in itself; it is a means to a better, more widely accepted decision.

-EPA Manual on Consultative Processes

¹⁹For more information on FACA, contact Vicki Ellis, Committee Management Officer (202.260.4999) or Chris Rice, Committee Management Secretariat (202.260.5986) or access the EPA Office of Reinvention website on stakeholder involvement: <http://www.epa.gov/reinvent/epastake/>.

group may be appropriate for your other stakeholders.

3.5 What Kind of Outreach Does RFA/SBREFA Require?

The RFA/SBREFA requires an agency to “assure that small entities have been given an opportunity to participate in the rulemaking process” for any rule that “will have a significant economic impact on a substantial number of small entities.” 5 U.S.C. § 609(a). RFA/SBREFA also directs us to ensure small entity participation through the reasonable use of techniques such as those listed in section 609(a), as follows:

- use of computer networks to solicit and receive comments
- publication of the notice of proposed rulemaking in publications likely to be obtained by small entities
- direct notification of interested small entities
- conduct of open conferences or public hearings concerning the rule for small entities;
- inclusion in an advance notice of proposed rulemaking, if issued, of a statement that the proposed rule may have a significant economic effect on a substantial number of small entities, and
- the adoption or modification of agency procedural rules to reduce the cost and complexity of participation in the rulemaking for small entities.

SBREFA also strengthened the RFA’s outreach provisions in two principal ways. First, the RFA now requires EPA to convene a Small Business Advocacy Review Panel (SBAR Panel or Panel) prior to proposing a rule for which we are required to prepare an IRFA (i.e., those rules for which EPA does not certify that the rule will not, if promulgated, have a SISNOSE). As described in detail in Chapter 4, the Panels are required to consult with representatives of small entities that will be subject to the rule. Second, the amended RFA allows small entities adversely affected by the final rule to sue agencies in court for failure to comply with specified RFA provisions, including section 609(a), which requires agencies to **assure** that small entities have an opportunity to participate in rulemakings that will have a SISNOSE.

3.6 Where Can I Get Assistance with My Small Entity Outreach?

You should first consult your Steering Committee representative to determine what resources are available to you within your program office. EPA also has several offices that may be able to assist you with outreach throughout different stages of rule development. EPA’s Small Business Ombudsman (SBO), located in OP’s Office of Regulatory Management and Information, can provide support and assistance in your outreach activities to small entities. The SBO maintains an updated list of key small

entity contacts, which will be made available to you upon request. These small entity contacts include:

- < national small-entity trade association executives and contact persons
- < contacts for the CAA State Section 507 Program, including the Small Business Ombudsman, Small Business Assistance Program, and the Compliance Advisory Panels; and,
- < EPA Regional Small Business Liaisons.

Additional support and assistance with outreach and development of small-entity contacts is available from the Office of Communications, Education and Public Affairs (OCEPA) Public Liaison Division, the Office of Policy's Regulatory Management and Information Division, Consensus and Dispute Resolution Team, and the Office of Congressional and Intergovernmental Relations (OCIR). Also, OCIR supports a small town FACA group, the Small Community Advisory Subcommittee of the Local Government Advisory Committee. OCIR assistance could include: 1) help creating an outreach strategy to support the rulemaking; 2) supporting the distribution of information; and 3) help developing and maintaining a comprehensive list of small entity contacts for use by individual program offices. Points of contact within EPA's OP, OCEPA, and OCIR are provided below (Section 3.8).

In addition to these general resources, each program office is encouraged to develop and maintain a comprehensive contact list of small entity representatives, keyed to their program area of responsibility. These could include:

- < small business trade associations; and
- < organizations representing townships, counties and municipalities, and decision-making individuals within these organizations (public and private non-profit).

You could use this contact list to help identify knowledgeable individuals who may serve as small entity representatives for your rulemaking.

EPA's Small Business Advocacy Chair (SBAC) is responsible for overseeing policy decisions regarding certifying that a rule will not have a SISNOSE, as well as decisions to convene a Small Business Advocacy Review Panel. The SBAC and SBAC staff are responsible for coordination of SBAR Panels, including communication with SBA and OMB and Panel logistics. Points of contact for the SBAC are provided in Section 3.8 (below).

3.7 What Steps Can I Take to Reach Small Entities?

The following sections outline some suggested steps you can take in developing a proposed rule, particularly if it appears that it may not be possible to certify that your rule will have no SISNOSE.

As noted above, you should also check with your Steering Committee representative to explore what resources are available to you within your own program office.

Contact SBAC staff

If you believe that it may not be possible to certify your rule as having no SISNOSE (according to the screening analysis in Chapter 2), you should contact the SBAC staff through your Steering Committee representative. The SBAC staff will work to provide you with the support and service needed to make each SBAR Panel process as efficient and productive as possible. SBAC staff can advise you on how the RFA/SBREFA Panel process can fit into your rulemaking schedule, potential inclusion of SBA and OMB in outreach efforts, and the implications of the results of your screening analysis, among other things.

Identify and contact small entities

Stakeholders are those who have an interest -- direct or indirect -- in the action the Agency is planning to take. Small entities are a subset of your broader stakeholder group -- those that meet the statutory definition of small business, small government or small non-profit enterprise.²⁰ As part of your outreach efforts, you should make informal contact with potential small entities to confirm their small entity status.

There is an important distinction to note at this time between small entities which should be included as stakeholders through your broader outreach efforts and official Small Entity Representatives for a Small Business Advocacy Review Panel process. Official Small Entity Representatives are chosen through a process of consultation with the EPA Small Business Advocacy Chair and the Small Business Administration. This process is described in more detail in Chapter 4. While small entities with whom the Agency has consulted from the beginning are the chief candidates to serve later as official advisors to a Panel, **small entities do not become official Small Entity Representatives (known as SERs) until they are officially designated as such by the Small Business Advocacy Chair.** The formal selection of Small Entity Representatives is made after SBA's response to your formal notification from the SBAC, which is typically very close to the time a Panel convenes.

Consider drafting informal notification to SBA

During the outreach process, if you believe that your rule may not be able to be certified as having no SISNOSE (according to the screening analysis in Chapter 2), you should consider drafting an informal notification to the Small Business Administration. You should route both informal and formal notifications, as well as any communications regarding potential RFA/SBREFA issues, through your Steering Committee representative to the SBAC. Section 4.6.2 provides more information on drafting an informal notification. Outreach to small entities or informal notification to SBA do not represent an EPA finding that your rule will have a significant economic impact on a substantial number of small

²⁰ See Chapter 2 for more information on the definition of 'small entity.'

entities, nor does it commit you to preparing a regulatory flexibility analysis or convening a Small Business Advocacy Review Panel. Small entities can provide input to help the Agency ultimately determine if either of these activities are required. Further, they can offer ideas to help the agency formulate alternatives that achieve your environmental objective and do not impose a SISNOSE.

Conduct outreach to small entities (i.e., substantive engagement)

It is clear from the specific requirements set forth by RFA/SBREFA that Congress intended agencies to provide small entities with a meaningful opportunity to participate in the development of rules that may significantly affect them. One of the keys to fostering productive participation is effective outreach and exchange of information. In conducting small entity outreach, you should distribute sufficient information to your small entity representatives about your regulation so that they can provide you with informed feedback on the four elements of an Initial Regulatory Flexibility Analysis under section 603 of the RFA which Congress identified in SBREFA as key issues. Those elements are:

- A description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- A description of projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirements and the type of professional skills necessary for preparation of the report or record;
- An identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule; and
- A description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities.

For small entities, it is advisable to request comments in writing since these will be used later as part of your SBAR Panel convening document or as documentation of your factual basis for a certification of no SISNOSE (see also Keep Records section, below). You may want to include the SBAC and staff, OMB, and SBA in your outreach efforts. Much of the success of previous SBAR Panel processes can be attributed to the level of familiarity that the Small Entity Representatives and the Panel members (described in Chapter 4) have gained with provisions under consideration for the regulation, as well as with the program staff developing the regulation, prior to convening the Panel.

So long as you ensure genuine engagement with small entities, you can certainly include this responsibility as part of your overall outreach efforts. EPA's guidance on stakeholder involvement, *EPA Manual on Consultative Processes: Better Decisions Through Consultation and Collaboration*, Draft - October 1998, offers guidance as to what process to use for

public involvement in your rulemaking and what steps to take to maximize your outreach efforts. Sections 3.2 and 3.5 (above) list some suggested venues for small entity outreach and Chapter 7 also contains a list of resources for getting your information disseminated to the public. In conducting outreach to small entities, however, it is important to ensure these parties have an opportunity to address their concerns separately and specifically to the Agency. While small entities may participate in public meetings designed for a broader group of participants, such a forum should provide an opportunity for EPA to hear separately and particularly from smaller interests. A particular reason that the Congress passed, and the President signed SBREFA was to “level the playing field” by affording smaller interests a chance to be heard independently from competing interests, including large entities likely to be regulated.

Keep Records

For any rule for which the Agency is required to prepare a Regulatory Flexibility Analysis (see Chapter 2), you are responsible for keeping a record of your outreach efforts and including that record in the rulemaking docket for purposes of judicial review. It is crucial for you to demonstrate and document a pattern of dialogue with and outreach to all interested stakeholders with particular attention to the interests of small entities that may be subject to your regulation. For each meeting, formal or informal, with your stakeholders you should take notes regarding the major topics of discussion and create meeting summaries. You should append any materials you distribute or present, including agendas, outreach packages, fact sheets, and overheads to your meeting summaries.

It is also a good practice to maintain a file documenting outreach even for rules not requiring an IRFA. This will allow the program to demonstrate its adherence to the Agency’s standing policy of outreach and, when feasible, accommodation of small entities in any rule to which they will be subject. In addition, since the Agency can now be sued on the factual basis it presents supporting its certification that a rule does not impose a SISNOSE, it may prove necessary to demonstrate how the Agency considered small entities’ concerns in reaching its decision to certify.

3.8 Where Can I Get More Information?

Program Steering Committee Representatives

OAR: Tom Eagles, Tel: (202)260-5585, Email: eagles.tom@epa.gov

OPPTS: Angela Hofmann, Tel: (202)260-2922, Email: hofmann.angela@epa.gov

OSWER: Barbara Hostage, Tel: (202)260-7979, Email: hostage.barbara@epa.gov

OW: Cynthia Puskar, Tel: (202)260-8532, Email: puskar.cynthia@epa.gov

EPA Small Business Advocacy Chair

Tom Kelly, Director
Office of Regulatory Management and Information
Tel: (202) 260-4001

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Stuart Miles-McLean, Tel: (202) 260-8518, E-mail: miles-mclean.stuart@epa.gov
Jennifer Greenamoyer, Tel: (202) 260-7829, E-mail: greenamoyer.jennifer@epa.gov
Jennifer Kim, Tel: (202) 260-1045, E-mail: kim.jennifer@epa.gov
Patrick Easter, Tel: (202) 260-6843, E-mail: easter.patrick@epa.gov

EPA Small Business Ombudsman Program

Karen V. Brown
EPA Small Business Ombudsman
Tel: (202) 260-0490

Small Business Ombudsman Program Staff

<u>SBO Staff</u>	<u>Media/Regulatory Speciality</u>	<u>Telephone Number</u>
Robert Rose	Clean Air Act, and general assistance	(202) 260-1133
James Malcolm	Toxic Substances and Hazardous Materials	(202) 260-1616
Larry Tessier	Asbestos, Radon, and Lead	(202) 260-1946
Arnold Medbery	Clean Air Act, Water, Asbestos	(202) 260-1787
Thomas Nakley	Clean Water Act and general assistance	(202) 260-1863

In addition, the two EPA programs involved with small governments, small communities, and small non-profit organizations that also are available to provide assistance and support in outreach to small entities under SBREFA are:

Small Governments and Small Communities

Steve Wilson, Small Community Coordinator
Office of State and Local Relations
Office of Congressional and Intergovernmental Relations
Tel: (202) 260-2294

Non-profit Organizations

Margaret Morgan Hubbard, Director
Office of Communications
Office of Communications, Education and Public Affairs (OCEPA)
Tel: (202) 260-4454

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Chapter 4.

The Small Business Advocacy Review Panel Process for Proposed Rules

4.1 What is a Small Business Advocacy Review Panel?

A Small Business Advocacy Review Panel (SBAR Panel or Panel) is an additional means for small entities to provide input into certain EPA rulemakings to ensure that the unique concerns of small entities are carefully considered during the rulemaking process. The Small Business Regulatory Enforcement Fairness Act (SBREFA) amended the Regulatory Flexibility Act (RFA) to require EPA to convene a SBAR Panel for any proposed rule for which the EPA is required to prepare an initial regulatory flexibility analysis (IRFA).

The RFA requires that we prepare an IRFA for all rules which EPA is required by statute to publish a NPRM **unless** the agency certifies that the rule "will not, if promulgated, have a significant economic impact on a substantial number of small entities (SISNOSE)."²¹ If an IRFA is required for a proposed rule under the RFA, we must also convene a SBAR Panel. Each Panel consists of representatives from EPA, the Small Business Administration, and the Office of Management and Budget. Although the statutory name for the Panel refers only to small businesses, **each Panel must solicit and consider the concerns of all small entities directly regulated by the rule, including small governmental jurisdictions and small nonprofit organizations, in addition to small businesses.**

4.2 What are the Statutory Panel Requirements?

Since the RFA was enacted in 1980, RFA section 609 has required all agencies to facilitate small entities' participation in rulemakings that will have a significant economic impact on a substantial number of small entities (see Chapter 3 for further discussion of general outreach provisions).

²¹ Because the term 'significant economic impact on a substantial number of small entities' is cumbersome, it is commonly called a "SISNOSE". When we determine that there will **not** be a significant adverse economic impact on a substantial number of small entities, we call that a "No SISNOSE" finding or "making the RFA/SBREFA certification."

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SBREFA expanded RFA section 609 to require EPA to convene SBAR Panels to ensure that small entity representatives are involved in the development of certain rules.²²

Under RFA section 609(b), as amended by SBREFA, we must convene a Small Business Advocacy Review Panel for any rule for which the Agency is required to prepare an IRFA. If we exercise our discretion to make the RFA/SBREFA certification (i.e., certify that a proposed rule will have No SISNOSE), we do not need to convene a Panel. **Even if we convene a Panel, EPA may defer the decision to certify a rule until after a Panel has concluded its work.** Also, RFA section 609(c) authorizes us to convene a Panel for a rule that we intend to certify, but that we believe may have “a greater than de minimis impact on substantial number of small entities.” Section 609(b) requires that the Panel process occur **before** publication of the IRFA, which must be made publicly available at the same time the proposed rule is published, except in cases of emergency. Accordingly, we (generally) must convene a Panel **before** a rule is proposed.

Section 609(b) establishes the following statutory framework for the Panel process:

- For any rule subject to the Panel requirement, EPA is to notify the Chief Counsel for Advocacy of the Small Business Administration (SBA) and provide the SBA Chief Counsel with information on the potential impact of the proposed rule on small entities and the type of small entities that might be regulated.
- The SBA Chief Counsel has 15 days from receiving notification of a rule to identify individuals representative of the small entities likely to be regulated by the rule.
- EPA is to convene a review Panel consisting **only** of full-time federal employees, including representatives of the Agency office responsible for developing the rule, the Office of Management and Budget’s Office of Information and Regulatory Affairs (OIRA), and the SBA Chief Counsel.
- The Panel is to review any material EPA has prepared in connection with the rulemaking, including any draft proposed rule, and collect the advice and recommendations of each individual small entity representative selected by EPA, after consultation with the SBA Chief Counsel for Advocacy, on issues related to specific elements of an IRFA for the proposed rule under development. The specific elements of an IRFA are
 - < a description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;

²² The Occupational Health and Safety Administration is also subject to the Panel requirement.

- < a description of projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the record or report,
 - < an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule, and
 - < a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities.
- Not later than 60 days after EPA convenes the Panel, the Panel must report on the comments of the small entity representatives and the Panel’s findings with regard to the issues related to the IRFA elements listed above. The Panel report must be included in the rulemaking record.
 - In light of the Panel report, the Agency is to modify, where appropriate, the proposed rule, the IRFA or the decision on whether an IRFA is required.

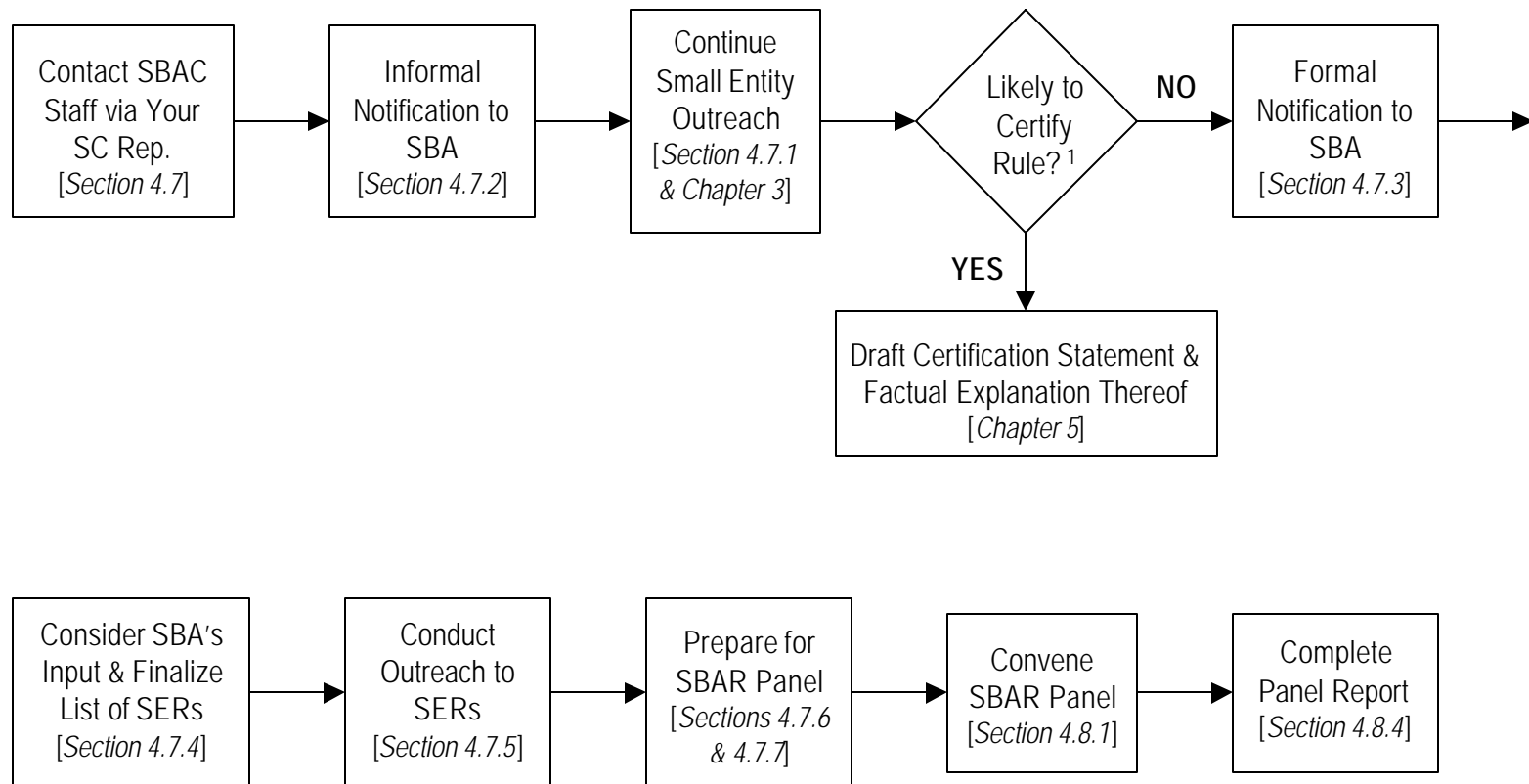
4.3 What Help is Available to Me in Preparing for a Panel?

First, you should check with your Steering Committee representative to see what resources are available to you within your own program office. EPA’s Office of Policy has created this guidance document which should answer most of your procedural and substantive questions about the SBAR Panel process. EPA’s Office of Policy also has a team of RFA/SBREFA experts who serve as staff to the SBAC to help you manage your Panel and answer questions before, throughout and after the Panel process. Each of these is described below.

4.3.1 How Can this Guidance Help Me with My Panel?

This chapter provides you with a step-by-step approach to implementing the SBAR Panel requirement. Our suggested approach is further illustrated in Figure 4. While the SBREFA amendments to the RFA establish the basic outline of the Panel process (described below), it also leaves us with discretion to determine many details of that process, including when to convene a Panel prior to proposing a rule. EPA has, therefore, developed a suggested process that will typically involve small entity representatives early in the rulemaking process. **Early involvement helps ensure that small entity comments and insights inform EPA’s thinking about fundamental issues of rule design and scope, as well as more specific issues posed by the particular regulatory program at issue.**

Small Business Advocacy Review Panel Process for Proposed Rules



Notes:

General: References to "Sections" in the flowchart refer to the sections in Chapter 4 in this guidance document (see Table of Contents). In addition, references to "Chapters" in the flowchart refer to the chapters in this guidance document.

¹ It is EPA's policy to assess impacts on small entities and minimize impacts to the extent feasible. If you do not have enough information to determine with confidence that the Agency can certify (no SISNOSE), proceed with "NO." The decision to certify can be made at any time before proposal.

Figure 4

This Guidance reflects agency policy and practice in implementation of the RFA/SBREFA. At the same time, we recognize the need for flexibility in implementing the RFA. Some rules subject to the Panel requirement may have developed in such a way that the Panel process must take place later in the rulemaking process than this guidance suggests. Nevertheless, this suggested process should work in most situations.

Our suggested Panel process is divided into several parts. You may not need to complete each part of the process if, during the course of rule development, you (or, more accurately, your Assistant Administrator, who is responsible to the Administrator for the certification decision) determine that your rule will not have a SISNOSE. However, even if your rule will **not** have a SISNOSE (i.e., you are making the RFA/SBREFA certification), but may have *some* impact on one or more small entities, it is important for you to engage in consultation with the relevant small entity stakeholders (see Chapter 3 on small entity outreach).

4.3.2 Who Will Help Me with My Panel?

Under SBREFA section 244(b),²³ SBAR Panels are chaired by a Small Business Advocacy Chairperson designated by the Administrator. The Chairperson is responsible for implementing the Panel review process. In 1996 Administrator Carol Browner appointed Tom Kelly, Director of the Office of Regulatory Management and Information of the Office of Policy, to serve as the Agency's first Small Business Advocacy Chairperson (SBAC). The Small Business Advocacy Chairperson heads a small staff (SBAC staff) who mainly work on RFA/SBREFA issues.

The SBAC Staff can help you in several ways. Two of the most important are:

- the SBAC staff serve as EPA's experts in the Panel process, providing support to program offices in resolving both complex and day to day issues, and
- the SBAC staff provide support for many of the mechanics of convening and operating the Panel.

An SBAC staff member will be assigned to work with you on your Panel. We encourage you to make contact with the SBAC staff as early as possible in the rule development process. This staff-level informal contact should also include your Steering Committee representative. You should also check with your Steering Committee Representative to explore what resources are available to you within your own program office.

²³SBREFA has several provisions that are not codified into the RFA but that still have an impact upon RFA implementation. SBREFA section 244(b) is one such provision.

4.4 What Circumstances Require EPA to Convene a Panel?

The first step you must take to determine whether we must convene a Panel is to conduct the screening analysis detailed in Chapter 2. As noted above, if your proposed rule may have a SISNOSE, you must prepare an Initial Regulatory Flexibility Analysis, and EPA must convene a Panel prior to proposal. Because the determination to convene a Panel can have a significant impact on your rulemaking schedule, you should identify the rule's potential impact on small entities as soon as possible. After the screening analysis is completed, you should consult with your Steering Committee Representative and the SBAC and SBAC staff. At this early stage, you should consider ways of structuring the rule to avoid any undue burden on small entities while still meeting the environmental objective of the statute. In doing so, you may find that it may be possible to certify the rule as having No SISNOSE.

As stated in Chapter 2, we believe that only rules which may have a significant **adverse** economic impact on a substantial number of small entities require an IRFA, since the primary purpose of the IRFA is to identify and address regulatory alternatives “which **minimize** any significant economic impact of the proposed rule on small entities.” (RFA section 603, emphasis added). Thus, if your rule will exclusively relieve regulatory burden, or otherwise have a positive economic effect on the small entities subject to the rule, your rule may be certified and, therefore, you are not required to prepare an IRFA or convene a Panel.

EPA's decision to convene a Panel is not a commitment to prepare an IRFA (for rule proposal), a FRFA (for rule promulgation) nor does it prevent you from certifying your proposed or final rule.

In any case, our decision to convene a Panel is not a commitment to prepare an IRFA (for rule proposal) or a FRFA (for rule promulgation), nor does it prevent EPA from certifying your proposed or final rule if its substance so warrants. In fact, each step in the RFA/SBREFA process, from informal notification through completion of the RFA/SBREFA Panel Report, leaves open the prospect that your rule can be certified as having no SISNOSE, should the provisions of your rule change or new information be discovered. For example, you may adopt Panel recommendations that would result in a proposed rule no longer having a SISNOSE. In that case, EPA could properly certify your rule and you would not be required to complete an IRFA or convene a Panel.

4.5 Can I Request a Waiver from the SBAR Panel process?

Under RFA section 609(e), EPA may request that the SBA Chief Counsel for Advocacy waive the Panel requirement for a rule. The SBA Chief Counsel may grant a waiver if he or she finds that convening a Panel would not advance the effective participation of small entities in the rulemaking process. (Note, however that the waiver applies only to the requirement to convene a Panel; it does

not relieve you from preparing an IRFA, notifying the SBA Chief Counsel of the rule or the SBA Chief Counsel from identifying small entity representatives.)

The SBA Chief Counsel will consider the extent to which you have already consulted with small entity representatives and taken their concerns into account; “special circumstances necessitating prompt issuance of the rule”; and whether the Panel process would provide the small entity representatives involved in the process a competitive advantage over other small entities. Before granting the waiver, the SBA Chief Counsel must consult with OIRA and the small entity representatives identified by the SBA Chief Counsel after receiving formal notification of the rule. The SBA Chief Counsel must also provide you with a written explanation of the waiver decision for the rulemaking record.

Your waiver request must be submitted through your Steering Committee representative to the Agency SBAC. EPA will only request the waiver of a Panel requirement in exceptional circumstances (e.g., when a rule is subject to a near-term legal deadline) or when you have already engaged in extensive outreach to representatives of potentially regulated small entities such that a Panel would be demonstrably redundant.

Even if the Agency decides to request a waiver, you, in cooperation with your Steering Committee Rep and SBAC staff contact, will still need to complete the formal notification step of the process as outlined below. The SBAC will also informally notify the SBA Chief Counsel of the Agency’s intent to request a waiver before formally requesting it. If the SBA Chief Counsel grants the waiver, you are not required to complete the remaining steps of the Panel process, but you should conduct as much outreach as time permits or as appropriate under the circumstances.

4.6 When Should We Convene a Panel?

It is EPA's policy to convene Panels relatively early in the proposed rule development process to give the Panel the best opportunity to inform decision makers during the initial stages of rule development (i.e., prior to option selection). This is balanced with the need for sufficient shape and development such that the small entity representatives and the Panel members will have adequate information to critically appraise EPA’s intention. Generally, the Agency SBAC will consult the other standing Panel members with respect to an appropriate time to convene a Panel. However, no matter when in the regulatory development process a Panel is convened, the Panel's final report must be completed within 60 days of convening the Panel. EPA expects that the Panel process will normally be concluded well in advance of Final Agency Review (or equivalent stage for Tier 3 rules), in order to be most useful to the development of the proposed rule.

4.7 What Should Be Done Before my Panel Can Be Convened?

Once you determine that we must convene a Panel for your rule, you should make contact with the SBAC Staff through your Steering Committee representative to find out who you will be working with on your Panel. You should share information about your expectations for the Panel process and the rulemaking schedule. Bear in mind that **the Panel itself should take no more than the 60 days provided by the statute to conduct its review; however, the entire Panel process -- once begun in earnest with focused small-entity outreach, through SBA notifications, preparation for and convening of the Panel and completion of the Panel report -- will usually take between four and ten months.** The amount of time is dependent on the complexity of the rule and the amount of outreach done prior to the initiation of the Panel process. This time line may require you to change your rulemaking schedule or resource commitments. When negotiating court schedules, program staff and management should take into consideration the time and resources that may be needed to comply with the RFA/SBREFA Panel requirement. However, the Agency will not ask for an extension of any court-ordered deadlines solely to comply with RFA/SBREFA Panel requirements, so it is vital that the program fully consider these responsibilities in setting its initial rulemaking schedule.

Prior to convening a Panel, the typical steps include:

- identifying and making contact with small entity representatives (SERs) among your stakeholders
- providing informal notification of the Panel to SBA and OMB
- creating a dialogue with your SERs
- providing formal notification of the Panel to SBA and OMB
- hosting a final pre-panel outreach meeting with the SERs to which SBA and OMB are invited
- participating in a pre-panel meeting with SBA and OMB staff to discuss available data and other related issues, and
- creating a convening document for the Panel.

You, as the program office representative or rulewriter, are responsible for each of these steps (discussed further below). Your SBAC staff contact and your Steering Committee representative are available to give you support, review drafts and provide you with examples of documents from previous Panels.

It is very important for you to keep records of all your small entity outreach efforts. An important part of convening your Panel will be demonstrating that your office has worked with small entities throughout development of the rule. When you begin to involve SBA and OMB in your small entity outreach efforts, it is important to ensure that your SBAC staff contact is also provided with any outreach material, notices, or announcements. Your SBAC staff contact keeps the Agency's official record of the Panel process including all communication between Panel members regarding Panel issues.

4.7.1 Identify and Contact Small Entity Representatives

After it is determined that you will need to convene a Panel and you make contact with the SBAC Staff through your Steering Committee representative, your next step in the Panel process is to identify potential small entity representatives that may be formerly appointed later in the process. Small entity representatives (SERs) are typically a subset of your broader stakeholder group -- those representative of *small* entities likely to be *directly* subject to your regulation. Specifically, EPA prefers that SERs be owner-operators of small business or organizations or small government officials²⁴ potentially subject to the rule. If this proves to not be practical, other representatives, such as trade associations that exclusively or at least *primarily* represent potentially regulated small entities may serve as small entity representatives. Other persons who wish to act as SERs must be evaluated on a case by case basis. To avoid the appearance of conflict of interest, you should apply a general “reasonable person” rule, that is, ask yourself if a reasonable person would conclude that this potential representative is capable of truly representing only the interests of small entities.

Small entity representatives (SERs) are typically a subset of your broader stakeholder group - those representative of *small* entities likely to be *directly* subject to your regulation.

For each rule, or group of related rules,²⁵ you should identify as early as possible what types of small entities are likely to be adversely affected by the rule, and what those adverse impacts are apt to be (to the extent feasible at this early stage). An important resource for the Panel process will be the list of small entities that you developed under Chapter 3 to support your rulemaking activities generally. Once you identify candidate SERs, you must contact them to confirm their small entity status and ask if they would agree to serve as a small entity representative for your Panel, if so requested. Unless the program is in a position to sponsor necessary travel, each SER is responsible for his or her own expenses. It is advisable to let any potential SERs know what to expect from an RFA/SBREFA Panel process. The SBAC staff have developed a handout (available from the SBAC staff, see Section 3.8 for contact information) that will answer questions such as:

- < Why Does EPA Need Small Entity Representatives?
- < What is an EPA Small Entity Representative?
- < Who Is Eligible to be a Small Entity Representative?

²⁴ Small businesses are defined by the Small Business Administration through the Small Business Act (codified at 13 CFR 121.201). See Chapter 2 for more information on the definition of ‘small entity’ for RFA/SBREFA purposes.

²⁵ RFA section 605(c) permits, but does not require, EPA to "consider a series of closely related rules as one rule for the purposes of" preparing an IRFA. In certain circumstances, it may also be appropriate to convene one Panel to consider a series of closely related rules as well.

- < Who Chooses Small Entity Representatives?
- < At What Stage in the Rulemaking Does the Panel Process Occur?
- < What Will Being a Small Entity Representative Entail?
- < What Will Be Done with Small Entity Input?
- < How Can I Get More Information?

More information and ideas regarding small entity outreach are detailed in Chapter 3. Although this stage of the process will most likely take place before your rule is drafted, you should provide each potential SER with an outline describing the important components of your rule and any significant alternative approaches under consideration. Indeed, these early discussions with your potential SERs may bring to light other ways of structuring the rule to avoid any significant economic impact on a substantial number of small entities, in which case a Panel need not be convened.

To the extent that comments from potential SERs (or any other information) confirm the rule is likely to have impacts warranting preparation of an IRFA, you must continue to prepare for the Panel process. If comments received or changes made to the rule so warrant, it may still be possible to certify your rule. You should always consult with the SBAC staff and your Steering Committee representative if you stop preparations for a Panel.

4.7.2 Prepare Informal Notification to SBA

Once you complete your screening analysis and it has been determined that your rule may have a significant impact on a substantial number of small entities, through your Steering Committee representative, you must request that the Agency SBAC give the SBA Chief Counsel **informal** notification that EPA is developing a rule that may be subject to the Panel requirement, and that EPA may shortly ask SBA to nominate small entity representatives according to the statutory procedure. This preliminary notification is a courtesy to the Chief Counsel for Advocacy in order to provide SBA time to inform itself about the rule and review its own list of small-entity contacts. At this time, the EPA SBAC will provide the SBA Chief Counsel with a Program Office staff contact (normally this will be you as the workgroup chair), and will also ask for an SBA staff contact. Typically, the SBAC sends the informal notification via e-mail, with a courtesy copy also directed to OMB. Keep in mind that SBAC staff are always available to facilitate communication with SBA staff. Again, because the office of the SBAC is responsible for keeping the Agency's record for each Panel, you should copy them on any written exchanges with SBA and OMB regarding the Panel process.

You will need to draft the informal notification for the EPA SBAC to transmit to SBA. The informal notification could include:

- the title of the rule and projected NPRM date,
- the statutory authority for this action and the environmental objective,
- an explanation of any alternatives that are or have been under serious consideration,

- the potential impacts of the rule on small entities, and
- list of any potential SERS already identified.

SBAC staff are available to help you with this task and a model informal notification is available from the SBAC staff, see Section 3.8 for contact information.

4.7.3 Prepare Formal Notification to SBA

To the extent that it continues to appear that your rule may have significant impacts on a substantial number of small entities, you should work through your Steering Committee representative to request that the Agency SBAC provide **formal** notification to the SBA Chief Counsel that a rule is being developed that may be subject to the Panel requirement. EPA transmits the formal notification in hard copy under the SBAC's signature with a courtesy copy directed to OMB. Formal notification triggers the SBA Chief Counsel's statutory obligation to nominate small entity representatives within 15 days of receiving the notification. Formal notification does **not** commit the Agency to convening a Panel. The program office may still learn as a result of further consultations with small entity representatives and the SBA Chief Counsel's Office, or further analysis, that the rule will not have a SISNOSE, and thus neither an IRFA nor a Panel would be required.

Beyond the basic rule identifying information, you should provide the SBAC with the following information for the formal notification:

- a description of the problem the rule is trying to solve;
- a list of the types of small entities likely to be affected;
- a list of potential small-entity representatives you've already identified, if any; and
- any material you have already shared with small-entity representatives.

The notice, prepared by you for the SBAC, will emphasize that the request to identify small entity representatives does not represent an EPA finding that the rule will necessarily have a SISNOSE, nor does it commit EPA to preparing a formal regulatory flexibility analysis or convening a formal Small Business Advocacy Review Panel. A sample of a formal notification to the SBA Chief Counsel is available from the SBAC staff, see Section 3.8 for contact information.

4.7.4 Respond to SBA Input; Complete Recommendations for Small Entity Representatives

In response to your formal notification to SBA, you will receive a list of suggested SERS from SBA's Chief Counsel for Advocacy through the Agency SBAC. If EPA's outreach has been strong, the Chief Counsel usually identifies individuals with whom the Agency has already been consulting, and adds new names from SBA's own experience. After consultation with your SBAC staff contact and SBA staff on the names under consideration, you should recommend an official list of SERS for appointment by the SBAC. You must take great care to ensure that SERS are truly representing small

entities likely to be directly regulated by the rule under consideration. It is better to take time to confirm a small entity's status than to be forced to exclude someone later if he or she is not eligible. As stated earlier, EPA prefers that SERs be owner-operators or officials of small entities potentially subject to the rule. Barring that, other representatives such as trade associations that exclusively or primarily represent potentially regulated small entities may serve as SERs, and SBA's Chief Counsel for Advocacy has sometimes nominated such second-level representatives (see Section 4.7.1 for more discussion of SER selection).

While the RFA authorizes you to select the SERs for the Panel process, you should ordinarily include the SERs identified by the SBA Chief Counsel among those you recommend for appointment unless you discover any reason that one or more should be considered ineligible. Before deciding **not** to recommend any SBA-suggested representative for the official list, you should consult with your SBAC staff contact. You can include among your recommendations additional small entities not suggested by SBA, but ultimately it is desirable that EPA reach consensus with the SBA Chief Counsel on the roster of small-entity representatives. The SBAC will rely heavily on the program's recommendations in appointing SERs for the Panel.

4.7.5 Conduct Outreach to Small Entity Representatives

There is additional information regarding small entity outreach in Chapter 3.

- You must provide the SERs with enough information about the rule for them to be able to judge the likely impacts of the rulemaking on small entities. Outreach materials could include any draft of the rule or preamble text, if such materials are available.
- You must solicit information, advice and recommendations on issues relating to the specific elements of an initial regulatory flexibility analysis (listed in Section 4.2) from each small entity representative.²⁶
- You should encourage SERs to put their comments and suggestions in writing for inclusion in the convening document and your rulemaking record.
- You should keep detailed records of the SERs' participation for later use in developing the rule and any regulatory flexibility analysis or certification for the rule. The outreach process may lead to, and help substantiate, a determination that the rule will **not** have a significant impact on

²⁶Small entity representatives can be consulted individually, particularly since the RFA requires that the Panel collect the advice and recommendations of "each" representative. If, however, you choose to consult with small entity representatives as a group, be careful not to solicit a group recommendation because issues under the Federal Advisory Committee Act (FACA) may be raised.

a substantial number of small entities. Also, document your outreach efforts.

If the outreach process indicates that there will be no significant adverse economic impact on a substantial number of small entities, it may be possible to certify your rule. In that case, the remaining steps of the Panel process would no longer apply to your rule.

4.7.6 Prepare a convening document for the Panel

The convening document is critical to the operation of a Panel. It provides the context and analytical framework for the Panel's deliberations and much of the Panel's report will be based upon the convening document you prepare. By following the outline suggested below, you will reduce the amount of work you must do to complete the Panel report. The organization outlined below has been used for most of the previous Panel reports, so it also offers the benefit of being familiar to the standing Panel members (i.e., Chair, OMB and SBA). The convening document should include the following information in approximately the following order:

1. Introduction;
2. Background and Regulatory History;
3. Overview of Proposal Under Consideration;
4. Applicable Small Entity Definitions;
5. Small Entities that May Be Subject to the Proposed Regulation;
6. Summary of Small Entity Outreach;
7. List of Small Entity Representatives; and
8. Summary of Input from Small Entity Representatives

You should attach copies of: any materials previously shared with the SERs and the written comments submitted by the small entity representatives to EPA as an appendix to the convening document. The convening document should **not** contain a discussion of the regulatory option or options actually selected by the Agency, since this document generally should be prepared before such decisions are made. The convening document should be forwarded to the SBAC staff assigned to your Panel at least one week prior to the convening date for the Panel. The SBAC staff are also available to review drafts of your convening document. A sample of a convening document is available from the SBAC staff, see Section 3.8 for contact information.

4.7.7 Consider a Pre-Panel Meeting with SBA and OMB

Recently, several program offices have consented to pre-Panel meetings with SBA and OMB to discuss information needs, and we have found this to be an increasingly valuable planning step. SBA and OMB tend to request a great deal of background information that they consider potentially relevant to developing significant alternatives to minimize burdens on small entities. At a minimum, SBA and OMB typically ask to review any materials that describe the regulatory alternatives under consideration

(to which small entities would be subject), their environmental rationale and/or benefits, and the costs they would impose on small parties, as well as the analysis and methods supporting these descriptions and estimates. SBREFA charges the Panel to review “any material the agency has prepared in connection with this chapter.” (“This chapter” refers to the RFA itself and suggests the elements of an IRFA, which include “a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities.”)

Since the full range of data and analysis needed to construct a publishable IRFA may not become available until relatively late in the rulemaking, the “materials the agency has prepared,” as well as their stage of completion and level of supporting detail at the time of convening, will vary from rule to rule. In effect, the Panel encounters the rulemaking as a work in progress, with the opportunity to affect its future development to avoid unnecessary burden on small entities. EPA supports the Panel’s thorough, meaningful consideration of such impacts and the design of justifiable accommodations for small entities. We seek to provide the Panel with whatever information may be available to promote those objectives, and it has been our practice to respond generously to SBA’s and OMB’s requests for existing data, reports, and surveys. Nevertheless, because each rule presents its own special circumstances bearing on what information is both available and relevant for the Panel’s review, a preliminary meeting to consider what materials the Panel will receive, as well as what may be suitably provided to our non-Federal advisors, may be useful in clarifying the expectations of all members. See further discussion of data needs under 4.8.2 below.

4.8 What Can I Expect from Panel Review?

Each Small Business Advocacy Review Panel is chaired by the Agency Small Business Advocacy Chair (SBAC). The three other statutory Panel members are:

- 1) an EPA senior manager from the Program Office developing the rule,
- 2) the SBA Chief Counsel for Advocacy and,
- 3) the Administrator of OMB’s Office of Information and Regulatory Affairs

Each of these officials signs the final Panel Report, though, as a practical matter, one or more may be represented by a designee during a portion of the Panel’s deliberations. The Panel member representing the EPA program should be a senior manager familiar with your rule who has the authority to negotiate the program’s position on potential regulatory alternatives for small entities. **Remember, small entity representatives (SERs) are not members of the Panel** -- they provide input to the Panel, but by statute the Panel comprises only Federal employees, as identified above.

4.8.1 When is the Panel Officially Convened?

The SBAC convenes the Panel at the first formal meeting of the Panel members. The SBAC sets the convening date in coordination with all the Panel members through consultation facilitated by the SBAC staff. The convening document and a program office presentation on the regulation are generally used as the main vehicles for initiating review. Once the Panel convenes, it is critical that all Panel members review the same set of information. Accordingly, during a Panel, all communication to the Panel members should be channeled through the SBAC's staff. **Materials not for public release can be marked deliberative and circulated to Panel members as Federal employees. Such materials will be kept confidential and will not be released to the public as part of the Panel Report.**

4.8.2 What Information Am I Required to Provide to the Panel?

The program office Panel member should be prepared to negotiate with SBA and OMB on the type and amount of data and supporting information that is needed to support the Panel's discussions. We have found that a pre-convening meeting can provide a useful forum for arriving at workable understandings on this matter, but unexpected issues can arise during the 60-day Panel term as well. SBA and OMB sometimes request information and analyses that have not yet been performed. As detailed below, according to the statute, the Panel is to review any existing RFA-related materials and any draft proposed rule, if those materials have been prepared by the time the Panel convenes. **The RFA does not require EPA to develop materials or perform analyses specifically for the Panel process.**

The following describes the information the RFA requires you to provide to the Panel:

- Draft regulatory text – Section 609(b)(4) states that “the panel shall review any material the agency has prepared in connection with this chapter, including any draft proposed rule.” This language does not require EPA to prepare a draft proposed rule prior to convening a Panel, however, if you convene the Panel after you have prepared a draft NPRM, you must provide it to the Panel members.
- Economic impact data – Section 609(b)(1) requires EPA to provide SBA “information on the potential impacts of the proposed rule on small entities and the type of small entities that might be affected.” Section 609(b)(1) does not specify the requisite level of analysis of the potential impacts. EPA does not believe the RFA requires you to prepare a full economic analysis of potential impacts for the Panel process, nonetheless, EPA clearly must provide some information - either quantitative or qualitative - on the potential impacts.
- Regulatory Alternatives – Section 603(c) requires the IRFA to include “a description of any significant regulatory alternatives to the proposed rule which accomplish the stated objectives of

applicable statutes and which minimize any significant economic impact of the proposed rule on small entities.” [Emphasis added] The RFA does not require you to prepare for comment by the Panel what essentially would be a draft IRFA for all regulatory alternatives you have identified. You do, however, need to describe in sufficient detail, including some analysis of the impact on small entities and environmental benefits, each significant regulatory alternative you have identified that accomplishes the statutory mandate. It is important to note that the Panel process precedes and is intended to contribute to the development of the IRFA, not the reverse.

- Technical and legal supporting materials – Pursuant to subsection 603(b)(2), an IRFA must address the legal basis for a proposed rule. However, section 603(b)(2) is not one of the expressly enumerated subsections on which the Panel is to collect advice and recommendations. Since the RFA places the legal basis for the proposed rule outside the purview of the Panel, the RFA does not require EPA to provide such information to the Panel.

Although the above list describes what the RFA does and does not require you to provide to the Panel, as a matter of policy, EPA typically provides information beyond the statutory minimum. When doing so, you should consult with staff to the SBAC and establish clearly that the provision of such information is not statutorily mandated. In previous Panel processes, several EPA program offices have made it a practice to provide requested information to the Panel as long as the information has been cleared by OGC for public release or otherwise would have been provided to any requestor. We have also honored requests for materials not already prepared if fulfilling the request would not consume excessive resources or delay the rulemaking/Panel schedule.

It is vital that program regulatory staff remain in close consultation with its own management to ensure that its provision of non-statutory information is neither inappropriately restrictive nor unacceptably intrusive on the program organization’s internal priorities and schedules. SBAC staff can be helpful to you in establishing how the Agency has viewed and treated similar requests for information in other Panel settings. (See 4.7.7 for further discussion of how we typically anticipate such requests and determine whether and when the Agency can fulfill them.)

4.8.3 Panel Outreach to SERs

The RFA also tasks the Panel with performing its own outreach to the Small Entity Representatives. Typically, this consists of a meeting with the SERs, either in person or via teleconference. Prior to this meeting, the Panel generally sends a letter or package of information to the Small Entity Representatives that provides them with enough information about the rule for them to be able to judge the likely impacts of the rulemaking on themselves and other small entities. The Panel agrees on the content, but development of this outreach package is the responsibility of the EPA program office responsible for the rule. The outreach letter will request written comments from each

small entity representative on the four elements of an IRFA (see Section 4.2) as well as other issues identified by the Panel. The program office should try to anticipate what information the Panel would like to provide to the SERs and develop the SER outreach package prior to convening the Panel. We encourage you to circulate the draft outreach package to the Panel members within one week of convening. The outreach materials are circulated and agreed upon by all Panel members before they are sent out under the signature of the SBAC. An example of an outreach package is available from SBAC staff, see Section 3.8 for contact information.

At the outreach meeting, chaired by the SBAC, the program office is generally responsible for a brief presentation on the proposal under consideration and the remainder of the time is devoted to feedback from and dialogue with the SERs. **The program office is responsible for creating a summary of this meeting for inclusion in the Panel report.** The SER outreach meeting should generally take place within the first 30 days of the Panel process.

4.8.4 Panel Deliberations/Generating the Panel Report

The Panel generally meets very soon after the SER outreach meeting to discuss the SER comments. It is useful at this point, for each Panel member to be able to bring to the table proposals for regulatory options that may minimize economic impacts on small entities. Panel deliberations can occur through a series of face-to-face meetings of the Panel members (or their designees), conference calls, e-mail exchanges or facsimile transmissions. Deliberations generally center around the language that will be contained in the Panel report. You should be prepared to devote a significant amount of time and effort to drafting materials for your SBREFA Panel, especially toward the end of the 60-day process. **The program office has the primary responsibility for drafting the Panel report.** The first complete draft of the Panel report is based primarily on SBA and OMB's input (based on the SER comments) to the convening document. Each of the Panel members will sign the completed Panel report; therefore, each Panel member has a vested interest in the specifics of the Panel report language. The program office Panel member should be prepared to negotiate with OMB and SBA on Panel recommendations; this could require a substantial amount of time as well as direct, immediate feedback from management.

By statute, the Panel only has 60 days from the date it is convened to produce its official final report. The Panel is not required to take the full 60 days, and should issue its report as soon as possible to provide timely input to the development of the proposed rule. The Panel need not reach consensus in order to issue a final report; the views of each of the members can simply be reflected in that report. When possible, the report should state matters of Panel agreement, but no Panel member is under compulsion to agree to any position. Indeed, any member may demur and even insert into the Panel Report a contrary position, with the knowledge that the Report will be part of the public record offered for comment when the proposed rule is published. Since an EPA program office representative signs the Panel Report, **it is generally recognized that any recommendations agreed upon by the entire Panel are acceptable to the Agency, whether as modifications to the regulatory**

proposal, or as issues to be discussed in the preamble. Even if there are subsequent data findings or circumstances that warrant a change in EPA's position after the Panel closes, it is important to discuss the Panel's recommendations and the Agency's response in the NPRM. The program office Panel member should not agree to any Panel recommendation if it appears that the agency cannot implement it. The final Panel report will **not** contain a discussion of the option or options actually selected by the Agency, since the report will normally be prepared before such decisions are made.

4.9 Consideration of the Panel Report during Development of the Proposed Rule and Initial Regulatory Flexibility Analysis

The RFA requires the Agency to consider the Panel report in selecting proposed regulatory options to address small entity concerns, and where appropriate, to modify the proposed rule, the initial regulatory flexibility analysis or the decision on whether an initial regulatory flexibility analysis is required. As stated earlier, it is generally recognized that any recommendations agreed upon by the entire Panel will be addressed in the proposed rule unless unforeseen circumstances intervene between completion of the Panel report and the time of proposal. You should document the results of the outreach and Panel process, and their role in the Agency's deliberations in the initial regulatory flexibility analysis prepared for the rule. You should integrate the substantive Panel recommendations into your preamble text in the appropriate sections and also summarize these results in the Regulatory Flexibility Section of the preamble of your proposed rule. The Regulatory Management Division of EPA's Office of Policy, which is responsible for the review of regulations prior to OMB review and signature by the Administrator, will, in conjunction with OGC, ensure that your preamble language is sufficient.

EPA's policy is to keep the Panel report confidential until the rule is proposed, since we consider its recommendations to be protected as part of the Federal deliberative process. Upon proposal, the Panel report must be placed in the docket for the rulemaking so that it will be accessible to all parties interested in the rulemaking.

Chapter 5.

Small Entity Compliance Guides

5.1 EPA'S Approach to Small Entity Compliance Guides

When the Agency is required to prepare a regulatory flexibility analysis for a final rule, SBREFA Section 212 also requires the Agency to:

- prepare and publish one or more documents regarding such a rule or group of rules as small entity compliance guides and specifically “designate such as small entity compliance guides;”
- explain in the compliance guide actions that a small entity must take to comply with a rule or group of rules; and
- distribute the guides to small entities through “comprehensive sources of information.”

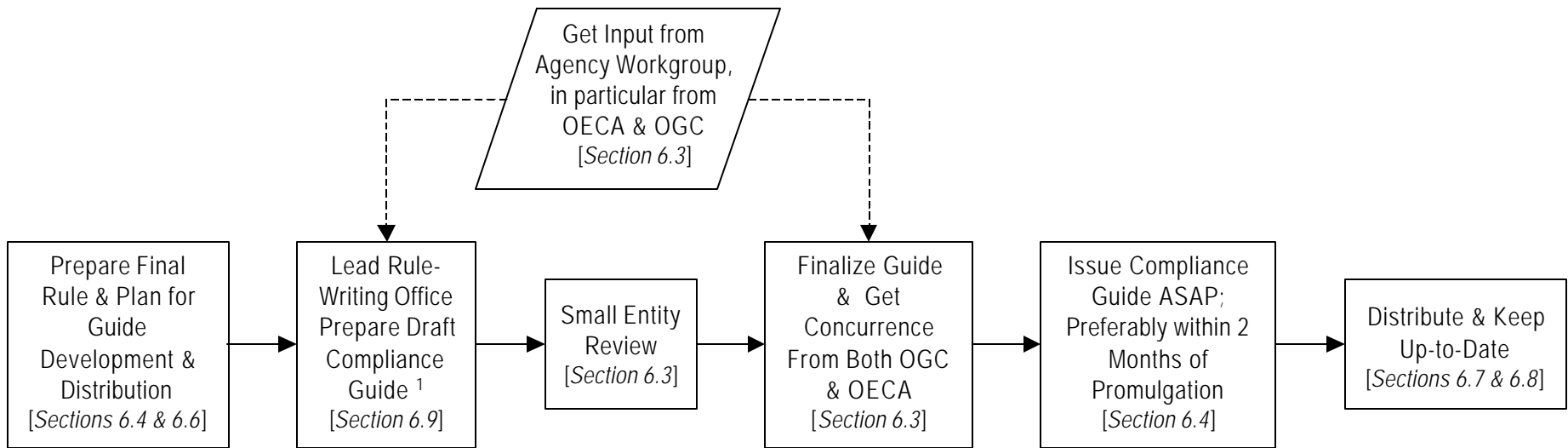
While compliance guides are not judicially reviewable, they may be considered as evidence of the reasonableness or appropriateness of any penalties or damages in any civil or administrative action against a small entity. Accordingly, the statute gives us broad discretion with regard to implementing these requirements particularly in regard to designation, development and distribution of the guides. Although guides are required only for final rules for which a regulatory flexibility analysis was prepared, rulewriters should start their planning for the guide during the proposed rule phase. Timing is discussed further in Section 5.4

The sections that follow describe how the Agency has chosen to exercise this discretion, the specifics of which may not necessarily be required by SBREFA. As we gain experience, we may issue additional guidance. Figure 5 illustrates our approach to developing a small entity compliance guide.

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Small Entity Compliance Guides



Notes:

General: References to "Sections" in the flowchart refer to the sections in Chapter 6 in this guidance document (see Table of Contents).

¹ If you are doing an Analytic Blueprint you should include plans for developing the guide, including a timeline, and the resources needed. If there is no Blueprint, you should integrate Compliance Guide development into your action or work plan.

Figure 5

5.2 What is the Goal in Writing a Compliance Guide?

As mentioned above, SBREFA Section 212 requires that Agency to prepare and publish one or more documents regarding such a rule or group of rules as small entity compliance guides and specifically “designate such as small entity compliance guides.” Beyond meeting the statutory obligation, the primary goal of the guide is to help small entities-- whether they are small businesses, small governments or small non-profit organizations-- to comply with the regulation. You should therefore write your guide with your audience in mind and recognize that this segment of our regulated community may have trouble with standard government writing styles. President Clinton’s memorandum of June 1, 1998 entitled “Plain Language in Government Writing,” requires agencies to use plain language in all documents that explain how to obtain a benefit or service or comply with a regulation. You should focus your guide on what a small entity will need to know to comply with your regulation and minimize the inclusion of any other information (see the template in section 5.10, below). While small entities are the primary audience for the guides, some of the compliance information may also be applicable to large entities and you may choose to present these similarities/differences as you develop your guide.

5.3 Who Participates in the Development of a Compliance Guide?

The lead rule-writing office is responsible for developing the rule-specific compliance guide as part of the rulemaking process. You should have your draft guide reviewed by both the Office of General Counsel attorney assigned to your rule and by a representative from OECA. Your regulatory development workgroup, as well as representatives from SBO, OPPT’s Pollution Prevention Division, regional offices and the SBAC’s staff can also provide assistance/support, or develop sections of the guide, as appropriate. If your regulatory development workgroup does not include representatives of the appropriate offices, you should work through your Steering Committee representative to identify such individuals.

Small entity representatives should typically be involved in reviewing the draft compliance guide after the rule is promulgated so that we have the benefit of their comments and advice in preparing the final version of the guide. Generally, draft compliance guides should not be released to outside parties prior to the rule’s promulgation. In those unusual circumstances where the outline of the compliance guide is clear to you at pre-proposal, then you may seek review and feedback from small entity stakeholders at that stage. You should share the draft compliance guide and solicit comment from small entity stakeholders after promulgation, but will need to balance such review with equal concern for timely issuance of the guide.

You will need to obtain concurrence from both OGC and OECA. Normally, you will ask members of your workgroup from these offices to ensure that appropriate levels of management in their offices approve the draft. (OGC and OECA will determine the level of concurrence they need within their offices.)

5.4 When Should I Develop a Compliance Guide?

You should integrate development of the guide into the rulemaking process. Generally, you should begin work on your guide as soon as you have enough information to do so. This point will vary from rule to rule; sometimes it is clear even before the rule is proposed, and in other cases not enough is known until just prior to final promulgation. In either event, **you should plan to devote time during the rulemaking process for development of a guide, however, the Agency will not ask for an extension of any court-ordered deadlines in order to complete compliance guides.**

Keep in mind that the goal is to make the guide available after promulgation in sufficient time for it to be of practical help to small entities in evaluating and implementing their compliance options before the compliance deadline. You should make every effort to issue the guide **within two months of the promulgation of the final rule.**

The constraints on outside participation during the final rule phase in development of the Guide leave a relatively short time after promulgation to both take comment from small entity stakeholders and issue the final Guide. This makes advance planning and drafting essential.

Tip: Identify your small entity reviewers early in the process. You may want to consider using those small entity representatives who participated in the Panel process during the development of the proposed rule.

If the issuance of your guide may be delayed beyond a month or two, you should issue a Fact Sheet or other brief description of the rule as an interim measure. If your rule has a distant compliance date (e.g., two years or more), closer to the compliance date you may want to ensure the information in your compliance guide is still current and re-issue the guide, if appropriate.

5.5 What Sorts of Questions Should I Ask My Small Entity Reviewers?

Some suggestions include:

- C Is the format appropriate?
- C Is the guide clear and easy to read and understand?
- C Does the guide accurately describe the rule as published?
- C Is the guide useful in planning for compliance?

5.6 How Do I Document Development of the Guide?

If you are doing an Analytic Blueprint, it should include plans for developing a small entity compliance guide, including a time line, and the resources needed. If there is no Blueprint, you should integrate development of a compliance guide into your action or work plan. When you submit your final rule to the Administrator for signature, you must also submit a schedule for development and completion of a compliance guide. Include your distribution strategy for the guide in your Communications Plan. Information related to the development of the guide will be tracked in OP's Rule and Policy Information and Development System (RAPIDS). Lead offices are also encouraged to develop internal methods for tracking the development of the guides.

5.7 Who Can Help Me with Distribution?

In addition to internal office distribution mechanisms, you should provide copies of your completed Guides to the staff of the Small Business Advocacy Chair, the Office of the Small Business Ombudsman, the Office of Regional and State/Local Relations, and the Office of Communications, Education and Public Affairs. These offices will distribute the Guide to their small entity contacts. (You should ensure, to the extent it is feasible, that these offices do not have duplicate distribution lists.). Small entity compliance guides should be included in the Agency's Enhanced Public Access system which makes agency guidance documents related to statutory and regulatory requirements electronically available, for more information on this system, contact your Steering Committee representative (contact information is provided in Section 3.8). Other small business assistance providers include:

- C State Technical Assistance Programs for Pollution Prevention
- C State Small Business Assistance Programs
- C Small Business Development Centers
- C Trade Associations
- C Professional Organizations
- C the Small Business Administration, USDA and OSHA

A copy of your small entity compliance guide should be placed in the docket for your rule.

5.8 How Do We Ensure that Compliance Guides are Kept Up to Date?

As a statutory matter, compliance guides may have evidentiary uses in litigation so it is important that guides are reviewed and revised as needed. The guide should be revised when the rule for which it was developed is revised. It is the responsibility of the lead office to ensure compliance guides are kept current.

Other circumstances that may cause you to revise the compliance guide include:

- C Changes in the rule which affect compliance
- C Comments from the public suggesting revisions, or from OECA based on their experience in enforcing the regulation.
- C Litigation citing a guide as a reason to challenge the appropriateness of proposed penalties.

You should include in every compliance guide the following disclaimer on the cover page of your guide to inform small entities that the guide may be revised in the future and that it may be used in determining appropriate penalties in the case of non-compliance. You also should send a copy of your compliance guide to EPA's Small Business Ombudsman's office and place the most current guide in the appropriate docket, on a special section in EPA's internet page, or other electronic bulletin boards and the guide should also be included in the agency's Enhanced Public Access system.

NOTICE

This guide was prepared pursuant to section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 ("SBREFA"), Pub. L. 104-121. The statements in this document are intended solely as guidance to aid you in complying with **[insert name of your rule and its CFR citation]**. In any civil or administrative action against a small business, small government or small non-profit organization for a violation of the **[insert the name of your rule]**, the content of this guide may be considered as evidence of the reasonableness or appropriateness of proposed fines, penalties or damages. EPA may decide to revise this guide without public notice to reflect changes in EPA's approach to implementing **[insert the name of your rule]** or to clarify and update text. To determine whether EPA has revised this guide and/or to obtain copies, contact EPA's **[insert Small Business Ombudsman Office and phone number and name of Program Office that issued the rule and its main phone number and/or website address]**.

Note: OECA may, at a later date, develop sector-specific, multimedia guides which would integrate rule-specific guides. OECA will notify program offices if and when it undertakes this project and will coordinate development of such guides through the Agency's Regulatory Steering Committee.

5.9 Template for Compliance Guides

An Agency workgroup has developed the following template to help you in structuring your

compliance guide, and you should use it in accordance with the guidance given earlier in the chapter. While SBREFA does not mandate a particular format, we urge you to adopt it so that we may have general consistency across the Agency and to assure that significant compliance issues are adequately covered. If your rule does not, for some reason, lend itself to this template, you may use it as a checklist to ensure that all potentially relevant compliance issues are covered.

The template is organized as follows:

- C Non-italicized text indicates sections which should normally be included in the compliance guide.
- C Italicized text indicates standard language which you may choose to use if it is appropriate to your rule. You should adapt this standard language to the specifics of your rule as necessary.
- C Program offices have lead responsibility unless otherwise designated in **bold**.

Please make your best effort to write your guide in plain language using the guidance at <http://www.blm.gov/nhp/NPR/plaineng.html>.

[Insert standard publication header, including the date and appropriate publication number]

SMALL ENTITY COMPLIANCE GUIDE
[insert title of rule or program...]

INTRODUCTION

This document is published by the Environmental Protection Agency (EPA) as our official compliance guide for small entities, as required by the Small Business Regulatory Enforcement Fairness Act of 1996. Before you begin using the guide you should know that the information in this guide was compiled and published on [INSERT PUBLICATION DATE]. EPA is continually improving and upgrading its rules, policies, compliance programs, and outreach efforts. You can determine whether EPA has revised or supplemented the information in this guide by calling [INSERT HOTLINE NUMBER OR INTERNET ADDRESS].

Who Should Use this Guide?

1. To the extent possible, the guide should identify all the types/categories of small entities that will be subject to the rule's requirements. Bear in mind that other entities may be *indirectly* affected but may not be required to comply. This section needs to make this distinction clear to the reader.

Tip: Use the compliance table from the "Summary" section of your rule's preamble to convey this information. Be sure to modify it if necessary to target small entities.

2. In many cases, the guide will also be useful to larger entities subject to the rule. You may wish to point out any similarities or differences at this stage but you should not go into great detail on this subject.

What does the Guide Cover?

How do I use the Guide?

How do I Obtain a Complete Copy of the Rule?

List an 800 number, *Federal Register* citation or the Government Information Locator Service.

WHAT DOES THE REGULATION REQUIRE?

What environmental/human health issue(s) does this rule address and why it is important?

Summary of the New Regulation

1. Using plain English, summarize the rule in a narrative format. This should be a simplified adaptation of the issues you discussed in the rule's preamble.
2. Additionally, provide a visual description (e.g., chart or flowchart) of the rule's requirements as it applies to small entity operations or processes. "Operations" include traditional facility-based operations and non-

traditional based operations such as farms, communities or schools.

Compliance Timetable

Identify in easy-to-read format (e.g., flowchart, time line, timetable) compliance dates for notifications and other requirements.

How Does this Regulation Relate to Other Federal, State, and Local Requirements?

1. Each Program should develop specific template language concerning program delegations and relationships to other requirements **generally**, or, where appropriate, referring back to general provisions applicable to all regulations in a subgroup to which the new regulation belongs (e.g., New Source Performance Standards under the Clean Air Act). Programs have the flexibility to expand this section as appropriate, to address this issue more **specifically**.
2. Meanwhile, here is suggested template language which may be appropriate in many cases:

This compliance guide explains your federal compliance obligations with respect to _____ rule. There may be other state or local requirements which apply to you which are different from, or more stringent than, the federal requirements. For example, some environmental statutes allow EPA to delegate environmental programs to a state. The state may then promulgate its own rules which may supersede the federal requirements. For more information on the rules that apply in your State, please contact [INSERT CONTACT POINT].

STEP-BY-STEP PROCEDURES FOR COMPLIANCE WITH THIS RULE

This is where you break down the rule into discrete subject areas using a step-by-step, question/answer approach. Questions in this section will depend on the particular rule. All the following questions are EXAMPLES of the types of questions that may be appropriate to include.

How can I tell if I am subject to this rule?

What requirements am I subject to?

When do I need to comply ? (elaborate on flowchart, as appropriate)

What do I need to do to comply?

Be sure to address such questions as:

- C How does this rule affect my existing permit?
- C How much will it cost to comply with this rule?

What, when and how must I monitor or test?

What records do I need to keep and for how long?

Include sample forms and calculations.

What, when and to whom must I report?

Include sample forms.

How do I minimize harm if I think I am out of compliance? (Program lead/OECA support)

Where do I go for help?

Give information on federal, State and local contacts, Agency hotlines, or State Small Business Assistance Program contacts.

What is pollution prevention and how can it affect my operations? (OPPT lead)

1. Discuss pollution prevention and its benefits, including how it may be used to help a facility/operation save money and/or possibly avoid regulation.
2. To the extent that there are other pollution prevention opportunities, including those which may make good business sense or could exempt a small entity from certain requirements, the program, with support from OPPT, has the option to expand this section and include

this information.

Are there opportunities for flexibility or waivers?

If this is applicable in a given rule, these opportunities can be highlighted here. For example, there are circumstances in which the Safe Drinking Water Act allows temporary variances or exemptions from maximum contaminant levels.

OPTIONAL QUESTIONS AND ANSWERS ABOUT FACILITY/ OPERATIONS/ PROCESSES

Here you want to anticipate questions of potential concern to the regulated community, including how the rule fits into the overall regulatory program. Questions will depend on the rule; the questions below are only EXAMPLES. [Tip: A self-audit checklist can be very helpful to small entities and may be used alone or in conjunction with a question and answer format.]

How do I conduct a self-audit of my facility/firm/operation to help me evaluate whether I am in compliance with this rule?

Provide Self-Audit Checklist (Program/OECA)

What are the implications of this rule for my existing permits?

Adapt this to your particular rule or program.

How Does this Rule Change How I Handle/ Store Wastes? (if guide were written for RCRA rule)

THE COMPLIANCE ASSURANCE PROCESS (OECA LEAD)

This section should describe in clear, non-threatening terms why compliance is important, the potential consequences of violating the law, and how the entity can work with us to identify and correct its compliance problems, often without the need for a formal enforcement action or penalty.

Draft this section to ensure that small entities understand:

- C how EPA determines compliance
- C what they must do if they discover a violation, and
- C the available compliance assistance/enforcement options.

Include only information that is directly relevant to the rule. You may attach more detailed information, or information you feel may be helpful, in an Appendix.

How Is My Operation's Compliance With Environmental Requirements Determined?

Discuss compliance assistance, inspections, self-monitoring and the role of citizens.

If I Discover a Violation, How Can I Work With The Agency to Correct It?

Discuss compliance incentives policies: Small Communities Policy, Policy on Compliance Incentives for Small Businesses, Self-Disclosure Policy.

If the Agency Discovers a Violation, What Might Be Its Response?

To maximize compliance, EPA implements a balanced program of compliance assistance, compliance incentives, and traditional law enforcement. EPA knows that small businesses which must comply with complicated new statutes or rules often want to do the right thing, but may lack the requisite knowledge, resources, or skills. Compliance assistance information and technical advice helps small businesses to understand and meet their environmental obligations. Compliance incentives, such as our Small Business Policy, encourage persons to voluntarily discover, disclose, and correct violations before they're identified by the government. EPA's strong law enforcement program protects all of us by

targeting persons who neither comply nor cooperate to address their problems.

EPA uses a variety of methods to determine whether businesses are complying, including inspecting facilities, reviewing records and reports, and responding to citizen complaints. If we learn a person is violating the law, EPA (or a State, if the program is delegated) may file an enforcement action seeking penalties of up to \$[INSERT STATUTORY MAXIMUM AMOUNT], per violation, per day. The proposed penalty in a given case will depend on many factors, including the number, length, and severity of the violations, the economic benefit obtained by the violator, and its ability to pay. EPA has policies in place to ensure penalties are calculated fairly. These policies are available to the public. In addition, any company charged with a violation has the right to contest EPA's allegations and proposed penalty before an impartial judge or jury.

In summary, EPA recognizes that we can achieve the greatest possible protection by encouraging small businesses to work with us to discover, disclose, and correct violations. That's why we've issued self-disclosure, small business, and small community policies to eliminate or reduce penalties for small and large entities which cooperate with EPA to address compliance problems. In addition, we've established compliance assistance centers to serve over a million small businesses. For more information on these and other EPA programs for small businesses, please contact [INSERT POINT OF CONTACT].

What is the legal status of this guide?

A judge can look at a compliance guide in determining what penalty is appropriate and reasonable, although the content of the guide cannot otherwise be reviewed by the court.

In this Compliance Guide, we have tried to make clear what you must do to comply with the applicable

law and regulation. This is the minimum required by SBREFA. You'll notice, however, that here and there we have also included suggestions for alternative approaches that may make compliance easier and possibly even reduce costs. We hope you find this presentation of regulatory requirements useful and the additional information helpful in reaching and maintaining compliance.

APPENDIX

Glossary of Environmental Terms

Define terms which are relevant to the rule but which may be too basic to be defined in the rule itself. For example, "permit," "pollution prevention," "process."

Where to Obtain More Information

This section gives supplemental information. Examples might include other existing quality compliance guidance, pollution prevention guidance, pollution prevention case studies, other media contacts, trade associations, or university assistance programs.

Questionnaire - How Useful Was This Guide?

Each guide should contain a brief questionnaire to solicit feedback from users as to the usefulness, readability, and improvements needed for the guide. Questionnaires will be returned to OP/RMD and then forwarded to the Agency contact. Please use the following page:

Date: _____

Title of Rule or Program: _____

Name of Commenter (optional): _____

Please take a moment to let us know if you found this guide useful by answering the following questions. Thank you, your feedback is important to us.

1. *I could easily understand what requirements I must meet.* _____
2. *The guide is written in understandable language.* _____
3. *The guide helped me understand the steps I must take to comply with the rule.* _____
4. *If you have suggestions to improve the guide, please indicate below:*

----- Please fold on dashed line, affix postage and return by mail. Thank-you. -----

Affix
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**U.S. EPA
Regulatory Management Division
Mail Code 2136
401 M St. SW
Washington, DC 20460**

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Chapter 6.

Ongoing Informal Small Entity Guidance

This chapter provides a brief overview of our informal small entity compliance program and list of compliance assistance tools. A more detailed explanation of this program can be found in the *Section 213 Informal Guidance Program Report to Congress* (March, 1998) that can be obtained from OP's Regulatory Management Division at (202) 260-5480. **This information is provided here to help you understand what resources are available to assist you in your small entity compliance assistance efforts.**

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6.1 Overview of EPA's Section 213 Program

Section 213 of the Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement and Fairness Act (SBREFA) requires us to: 1) provide guidance to small entities "whenever appropriate in the interest of administering statutes and regulations", 2) establish a program for providing the guidance, and 3) to issue a report to Congress regarding the program. Under §213(a), we are required to answer inquiries from small entities regarding compliance with all agency statutes and final regulations. In particular, we are required to provide advice based on the application of the law to specific sets of facts supplied by small entities. **This advice and guidance can be considered as evidence of the reasonableness or appropriateness of penalties sought against a small entity.**

EPA's Informal Guidance Program consists of four main components:

- the Asbestos and Small Business Ombudsman (SBO), located at EPA Headquarters;
- regional small business liaisons, who serve as local resources to assist small entities who contact the EPA regional offices;
- various hotlines and clearinghouses that serve entities of any size, including large percentages of small entities; and
- technical and program staff located throughout Headquarters and the regions who are available to answer questions in their subject area or who refer small entities to the appropriate State and local resources.

In designing this program, EPA's guiding principles were: 1) to ensure the accessibility of the informal guidance program to the small entity community, and 2) to avoid duplication with existing activities. As provided in §213(b), we have applied existing functions and personnel in creating the program. By incorporating our Small Business Ombudsman (SBO) and other existing services into the

core of the Agency's Informal Guidance Program, we have been able to achieve both goals.

Organizationally, the SBO is located in the Office of Policy's Office of Regulatory Management and Information and reports to the Small Business Advocacy Chair. The SBO is already well-known in the small entity community, serving as a "first-stop shop" for multi-media compliance information. The SBO administers a free hotline handling approximately 1000 calls per month, answering fact-specific compliance questions, distributing supporting documentation, and providing information on additional sources of assistance. Callers may remain anonymous at their own discretion. In addition to these calls to the hotline, SBO staffers respond to another 1,000 or more calls annually that are made directly to their desks. Contact information for the SBO is listed in section 3.8 and the hotline information is listed below.

Informal small entity advice and guidance can be considered as evidence of the reasonableness or appropriateness of penalties sought against a small entity.

In addition to the SBO, EPA has numerous other resources to answer compliance questions from small entities, such as the small business liaisons, program-specific hotlines and clearinghouses, and technical and program media staff, some of which are listed below. For example, we sponsor approximately 89 hotlines and clearinghouses throughout Headquarters and the regions, which are available to customers of any size, including small entities.

We have a long history of developing authoritative materials to aid the regulatory community in its compliance efforts. These documents include such items as Sector Notebooks, Plain English Guides, and Fact Sheets. Through the issuance of such documents, you can often preclude the need for a small entity to contact us with a related inquiry. In addition to these written materials, you can make numerous resources easily accessible through the main EPA home page (www.epa.gov) or through your program office web site.

If you provide informal guidance to small entities, whether as a technical or program expert answering questions in your field of expertise or via a hotline or clearinghouse, you should be aware of a recent memorandum issued by the Office of General Counsel. The October 2, 1998 memo from Scott Fulton, Acting General Counsel, entitled "Treatment of Information Provided by Callers Seeking Compliance Assistance," provides guidance on the kinds of assurances EPA can make about the confidentiality of information provided by callers to EPA hotlines and is intended to apply to all EPA personnel providing informal guidance, in addition to hotline staff. As a matter of law, the Agency generally is unable to guarantee that any information received by EPA personnel or hotline staff will remain "confidential." As stated in EPA's SBREFA Section 213 Report to Congress, it is EPA's position that callers to an Agency hotline who request compliance assistance may choose to remain anonymous. Callers speaking with program or technical experts may similarly choose to remain anonymous. This means that the caller is not required to provide specific information such as her/her

name, phone number, or address, that could be used to identify the caller. The caller may simply choose to provide whatever information is necessary to describe his/her situation and to seek EPA's assistance in answering their questions. *Anonymity*, however, is not the same as *confidentiality*. For instance, EPA staff may not suggest or guarantee that (1) the information provided would not be viewed by other parts of EPA; or (2) the information would not be released by EPA to a third party if it were the subject of a Freedom of Information Act request.

6.2 List of Compliance Assistance Resources

EPA offers small businesses a wide variety of compliance assistance resources and tools designed to assist businesses in complying with federal and state environmental laws. These resources can help businesses understand their obligations, improve compliance and find cost-effective ways to comply through the use of pollution prevention and other innovative technologies. You and your management should assess which of these venues would be the most effective means to provide small entity compliance assistance regarding your rule.

Websites

EPA offers a great deal of compliance assistance information and materials for small businesses on the following Websites, available through public libraries:

# www.epa.gov	<i>EPA's Home Page</i>
# www.smallbiz.enviroweb.org	<i>Small Business Home Page</i>
# www.epa.gov/sbo	<i>EPA's Small Business Ombudsman</i>
# www.smallbiz-enviroweb.org/state.html	<i>List of State Contacts</i>
# www.epa.gov.ttn.sbap	<i>Small Business Assistance Programs</i>
# www.epa.gov/oeca/polguid.html	<i>Enforcement Policy and Guidance</i>
# www.epa.gov/oeca/smbusi.html	<i>Small Business Policy</i>
# www.epa.gov/oeca/oc	<i>EPA's Office of Compliance Home Page</i>
# www.epa.gov/oeca/ccsmd/commpull.html	<i>Small Businesses and Commercial Services</i>
# www.epa.gov/oeca/ccsmd/mun.html	<i>Small Communities Policy</i>

Hotlines

EPA sponsors approximately 89 hotlines and clearinghouses that provide a free and convenient avenues to obtain assistance with environmental requirements. The Small Business Ombudsman Hotline can provide you with a list of all the hot lines and assist you with determining which hotline will best meet your needs. Key hotlines that may be of interest to you include:

# Small Business Ombudsman	(800) 368-5888
# RCRA/UST/CERCLA Hotline	(800) 424-9346
# Toxic Substances and Asbestos Information	(202) 554-1404
# Safe Drinking Water	(800) 426-4791
# Stratospheric Ozone/CFC Information	(800) 296-1996
# Clean Air Technical Center	(919) 541-0800
# Wetlands Hotline	(800) 832-7828

Compliance Assistance Centers

EPA has established national compliance assistance centers, in partnership with industry, academic institutions, and other federal and state agencies, that provide on line and fax back assistance services in several industry sectors heavily populated with small businesses. You can access each center directly, or from the main Small Business Compliance Assistance homepage at: www.epa.gov/oeca/mfcac.html.

# Metal Finishing	www.nmfrc.org
# Printing	1-888-USPNEAC or www.pneac.org
# Automotive	1-888-GRN-LINK or www.ccar-greenlink.org
# Agriculture	1-888-633-2155 or www.epa.gov/oeca/ag
# Printed Wiring Board Manufacturing	www.pwbrc.org
# Chemical Industry	1-800-672-6048 or www.chemalliance.org
# Transportation	1-888-459-0656 or www.transouorce.org
# Paints and Coatings	www.paintcenter.org
# Local Governments	1-877-TO-LGEAN or www.lgean.org

State Agencies

Many state agencies have established compliance assistance programs that provide on- site as well as other types of assistance. Please contact your local state environmental agency for more information. EPA's Small Business Ombudsman can provide you with State Agency contacts by calling (800) 368-5888 or (202) 260-1211.

Compliance Policies Incentive

EPA's Small Business Policy and Small Communities Policy are intended to promote environmental compliance among small businesses by providing incentives such as penalty waivers and reductions for participation in compliance assistance programs, and encouraging voluntary disclosure and prompt correction of violations. These policies can not be applied to enforcement actions that have already been initiated. Contact Karin Leff (202-564-7068) for information on the Small Business Policy and Ken Harmon (202-564-7049) for information on the Small Communities Policy.

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Chapter 7.

Periodic Review of Final Rules as Required by RFA Section 610

7.1 Introduction

The Regulatory Flexibility Act (RFA) generally requires agencies to examine the impact of their proposed and final regulations on small entities.²⁷ Under §610, the RFA also requires that agencies review rules which have a significant economic impact on a substantial number of small entities (SISNOSE) within ten years of promulgation. The Small Business Regulatory Enforcement Fairness Act (SBREFA), enacted in 1996, added a judicial review provision to the RFA, which means the Agency can be challenged in court as to its compliance with the provisions of this section on a rule-by-rule basis.

This Chapter . . .

This chapter provides information on:

- C identifying rules subject to review
- C performing a §610 review
- C ensuring your review meets §610 requirements
- C publishing your results

What's a Section 610 review?

In general, a §610 review involves:

- identifying a promulgated rule that was not certified, (i.e. did not contain a finding that there was no SISNOSE);²⁸

²⁷Small entities are defined as small businesses, small governments, and non-profits that are not dominant in their field, see Chapter 2 for more information.

²⁸ "Certification" means that the Agency determined that the rule had no SISNOSE, and stated this to be the case in the published rule, see Chapter 1 for more information.

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- determining if the rule should be amended, rescinded, or let stand, based on five statutorily prescribed factors; and
- documenting the review and conclusions within 10 years of the date the rule was promulgated.

7.2 How Do We Identify Rules for Review?

Only rules that were subject to the RFA and were **not** certified, are subject to §610 review. EPA's Office of Policy provides a periodic preliminary list of rules to Steering Committee representatives that were subject to the RFA, not certified, and published during the last ten years, using an electronic search of the Federal Register. This list should be verified by each program office.

7.3 Scheduling Section 610 Reviews

The RFA requires that we **complete** the review by the tenth year anniversary date of publication. You may undertake a review any time within ten years of publication of the original rule. Conducting the review close to the ten-year anniversary, however, allows a more focused perspective on any changed impacts on small entities.

We will use the Regulatory Agenda (published semiannually in the Federal Register) to provide public notice of the review. You must complete the review within one year of that public notice. You do not need to initiate or complete any regulatory action to amend or rescind the rule within that year.

7.4 Must We Review a Rule More than Once?

There is no requirement to review rules more than once. After you complete a review, and decide to rescind, amend or to let the rule stand, that completes the obligation under §610.

7.5 What If a Rule has been Subsequently Amended?

The original, final rule as published in the Federal Register is the basis for §610 review. In some cases, a subsequent amendment may eliminate impacts on small entities so that there is no longer a SISNOSE. Under these circumstances, when the original rule comes up for its section 610 review, you must be able to adequately document the elimination of the SISNOSE, and publish this finding in the "Completed Actions" section of the Regulatory Agenda.

If an amendment reduces, but does not eliminate, a SISNOSE, then you should evaluate the

need for a §610 review based on current guidelines for SISNOSE thresholds (see Chapter 2).

If a subsequent amendment has created, rather than eliminated, a SISNOSE **based on current guidelines for SISNOSE thresholds**, then the rule must be reviewed within ten years of the date of the published amendment.

7.6 Do We Review a Rule or a CFR Part or Section?

The RFA explicitly stipulates a review by rule, rather than by sections or parts in the Code of Federal Regulations (CFR). While we recognize that rules subsequently become amalgamated into the CFR and may lose their individual identity, the final rule as published in the Federal Register remains the basis for §610 reviews. You will need to decide on a case-by-case basis if the rule can be sufficiently separated from its context in the CFR to do an adequate review. Sometimes you may need, or want, to include additional regulatory material to conduct a coherent and meaningful review.

7.7 Can a Section 610 Review Be Deferred?

The RFA allows the head of the Agency to certify in a statement published in the Federal Register that a review of an existing rule is not “feasible” by the 10 year anniversary of the rule’s promulgation. In practice, however, the Administrator expects that program offices will initiate and complete the reviews within this time. Any extensions must be justified on a case-by-case basis and requested by the program AA. Your Steering Committee representative will manage the process for you if you must request an extension.

7.8 Conducting the Review

Once you have determined that your rule:

- is subject to the RFA, and
- was not certified, either at the time of promulgation or when amended, you are ready to

conduct the §610 review.²⁹ Bear in mind that §610 does not require that you initiate a regulatory action to rescind or amend a rule within the one-year review period. It only requires that you complete the review in that time frame, publish your determination, and explain the basis for your decision.

To conduct a section 610 review follow the three steps described below:

1. Before you begin your review, develop an entry for each rule for the “Prerule” section of the Regulatory Agenda, indicating that you will be conducting this review over the next year, and requesting public comment. Contact your Steering Committee representative for specific information about the semiannual Regulatory Agenda exercise.

T The “Prerule” entry must:

- C state your intent to review the rule under §610;
- C give a brief description of the rule;
- C explain the need for and legal basis of the rule; and
- C invite public comment on the factors listed below.

You should also indicate in the abstract the length of the public comment period. Normally, this is 60 to 90 days. (See Section 7.12 for an example of a “Prerule” §610 entry in the Regulatory Agenda).

2. You must specifically address and ask the public for comment on the following factors when performing a review under §610:
 - C the continued need for the rule;
 - C the nature of complaints or comments received concerning the rule from the public since promulgation;

²⁹ Over time, EPA's definition of SISNOSE has evolved to meet new statutory and administrative requirements, and therefore the threshold for performing a regulatory flexibility analysis has changed as well. If your §610 rule does not meet **current** guidelines for SISNOSE, you should take this into account when conducting the §610 review, e.g., if a final regulatory flexibility analysis was performed under a more expansive reading of SISNOSE, you should note this in a justification for letting a rule stand. For guidance on SISNOSE, see Chapter 2.

- C the complexity of the rule (i.e., can you make the rule less complex so that small entities can comply more easily?);
 - C the extent to which the rule overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and
 - C the length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the are affected by the rule. (Evaluate these factors to the extent that they affect small entities, not the entire regulated universe.)
3. Put the results of the review in your program office docket. You must explicitly consider **all** of these factors in your review, and document the results, either positive or negative.

7.9 Does the Line-by-line Review also Satisfy Section 610 Requirements?

A line-by-line reinvention review qualifies as a §610 review if you address the required factors stated above, request public comments, and adequately document the review. Contact your Steering Committee representative or OGC if you are not sure that the review meets the §610 requirements. In most cases you will need develop a separate “Prerule” entry for the §610 portion of the line-by-line review, and proceed with an independent analysis.

7.10 Announcing the Results of the Review

The results of this review--either to rescind, amend or leave the rule unchanged--will be published in the “Completed Actions” section of the Regulatory Agenda one year from the time it was identified as a “Prerule.” You should use the “long form”, i.e., the one that allows an abstract, so that you can explain your determinations. Supporting documents should be placed in the public docket. (See Section 7.13 for an example of “Completed Action” entries in the Regulatory Agenda.)

7.11 Follow-up to the Section 610 Review

You should follow any decision to amend or rescind the rule with an entry in the “Prerule” or “Proposed Rules” section of a subsequent Regulatory Agenda.

7.12 Example of “Prerule” *Regulatory Agenda* Entry

To initiate a 610 Review, you must prepare a Regulatory Agenda entry by completing an Action Initiation Form (AIF). Each office has different procedures for preparing and submitting their AIF's. Your Steering Committee Representative can tell you what the procedure is for your office. Steering Committee members are listed on the EPA Guide to Regulation Development intranet site in the "Roles and Contacts" section of the Reference Library. The address is: <http://intranet.epa.gov/rapids>.

TITLE: (NEW) Technical Standards and Corrective Action Requirements for Owners and Operators of Underground Storage Tanks (Section 610 Review)

AGENCY: EPA

REGULATORY PLAN: No

PRIORITY: Info./Admin./Other

REINVENTING GOVERNMENT: This action is not part of the Reinventing Government effort.

LEGAL AUTHORITY: 5 USC 610

CFR CITATION: 40 CFR 280

LEGAL DEADLINE: None

ABSTRACT:

In September 1988, the Environmental Protection Agency (EPA) promulgated regulations establishing technical standards and corrective action requirements applicable to underground storage tanks (USTs) (September 23, 1988, 53 FR 37082). EPA issued the UST regulations under the authority of sections 2002, 9001 through 9007, and 9009 of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 USC 6912, 6991, 6991(a) through (f), 6991(h)). They became effective December 22, 1988, and are applicable to underground storage tanks containing petroleum or substances defined as hazardous under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980. EPA performed a regulatory flexibility analysis for this rule and concluded that it may have a significant economic impact on a substantial number of small entities, namely *[identify which small entities we believed would be affected, i.e., small business, governments or non-profits. If you know what the impacts were, briefly describe them]*.

This gives notice that EPA will review the UST regulations pursuant to section 610 of the Regulatory Flexibility Act (5 USC 610). EPA solicits comments on the continued need for the rule; the complexity of the rule; the extent to which it overlaps, duplicates, or conflicts with other Federal, State, or local government rules; and the degree to which technology,

economic conditions, or other relevant factors have changed since the rule was promulgated. EPA also will welcome comments on any other aspect of the rule.

EPA continues to view this regulation as a vital component of State-EPA efforts to ensure effective detection, remediation, and prevention of UST releases in order to protect human health and the environment. EPA intends to continue to require compliance with the regulation. Until and unless the Agency modifies the rule, owners and operators of underground storage tanks will be expected to comply with all parts of the rule. The Agency performed a similar review 3 years ago and concluded at that time that there was neither a need for nor any significant stakeholder support for changes to the UST regulation.

TIMETABLE:

ACTION DATE FR CITE

Begin Review.....04/00/98
End Comment Period.....07/00/98
End Review.....09/00/98

SMALL ENTITIES AFFECTED: None

GOVERNMENT LEVELS AFFECTED: None

ADDITIONAL INFORMATION: SAN No. 1234

AGENCY CONTACT:

Irwin L. Auerbach,
Environmental Protection Agency
Solid Waste and Emergency Response
Mail Code 5401G
Washington, DC 20460
703 603-7139
RIN: 2050-AE57

7.13 Example Entry for Completed Section 610 Review

All of EPA's Regulatory Agenda entries are submitted to OMB via EPA's Rule and Policy Information and Development System (RAPIDS). Your pre-rule entry announcing the review (Regulatory Agenda Review Form) is still in RAPIDS, and you only need to enter the results of the review. Enter the results in the "**Completed**" section which is highlighted in **bold**, below. Insert the date the review ended, and insert either "Rule will remain in effect without modification", or "New rulemaking started, see SAN # (insert SAN# of newly started rulemaking)". Each office has a different system for updating and submitting Agenda entries. Your Steering Committee representative will give you appropriate instructions when it is time to prepare your Regulatory Agenda entry.

1999 Revised RFA/SBREFA Guidance for EPA Rulewriters

TITLE: (NEW) Technical Standards and Corrective Action Requirements for Owners and Operators of Underground Storage Tanks (Section 610 Review)

AGENCY: EPA

REGULATORY PLAN: No

PRIORITY: Info./Admin./Other

REINVENTING GOVERNMENT: This review is not part of the Reinventing Government effort.

LEGAL AUTHORITY: 5 USC 610

CFR CITATION: 40 CFR 280

LEGAL DEADLINE: None

ABSTRACT:

In September 1988, the Environmental Protection Agency (EPA) promulgated regulations establishing technical standards and corrective action requirements applicable to underground storage tanks (USTs) (September 23, 1988, 53 FR 37082). EPA issued the UST regulations under authority of sections 2002, 9001 through 9007, and 9009 of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 USC 6912, 6991, 6991(a) through (f), 6991(h)). They became effective December 22, 1988, and are applicable to underground storage tanks containing petroleum or substances defined as hazardous under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980. EPA performed a regulatory flexibility analysis for this rule and concluded that it may have a significant economic impact on a substantial number of small entities, namely *[Identify which small entities we believed would be affected, i.e., small business, governments or non-profits. If you know what the impacts were expected to be, briefly describe them]*. In the April 27, 1998 *Regulatory Agenda*, we indicated that we would perform a review of this rule in accordance with 610 of the Regulatory Flexibility Act. We are now announcing the completion of that review and our decisions based on that review.

We have concluded that this rule should remain in effect with no modification. *[Add a brief summary of the analysis that led you to this conclusion, and reference where full information may be found in the docket]*.

TIMETABLE:

ACTION DATE FR CITE

Begin Review.....04/00/98

1999 Revised RFA/SBREFA Guidance for EPA Rulewriters

End Review.....09/00/98

[If rule will be changed or modified, add:]

New rulemaking started: see SAN 1234

SMALL ENTITIES AFFECTED: none

GOVERNMENT LEVELS AFFECTED: none

ADDITIONAL INFORMATION: SAN No.1234

AGENCY CONTACT:

Irwin L. Auerbach,
Environmental Protection Agency,
Solid Waste and Emergency Response,
Mail Code 5401G,
Washington, DC 20460,
703 603-7139

RIN: 2050-AE57

7.14 Section 610 Judicial Review

The 1996 SBREFA amendments to the RFA gave small entities adversely affected by a rule the right to seek judicial review of our compliance with the requirements of section 610. A reviewing court has wide discretion in deciding what the appropriate remedy should be for an agency's failure to comply with section 610, including remanding the rule or deferring enforcement of the rule against small entities, unless the court finds that continued enforcement of the rule is in the public's interest.